APPENDIX 2.2: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions from Post-Marketing Data Sources

BNT162B2

Cumulative Reporting Period: Through 18-JUN-2022

Interval Reporting Period: 19-DEC-2021 Through 18-JUN-2022

Total Number of Cases: 507,683 (Interval) / 1,485,027 (Cumulative)

Total Number of Adverse Events (PT): 1,591,026 (Interval) / 4,964,106 (Cumulative)

MedDRA Version: v.25.0J

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal lymphadenopathy	41	9	17	17	24		
Abnormal clotting factor	13		8	1	5		
Acquired amegakaryocytic thrombocytopenia	1		1				
Acquired factor V deficiency	1	1	1				
Acquired factor VIII deficiency	2	1	2				
Acquired haemophilia	65	29	65				4
Acquired Von Willebrand's disease	3		3				
Activated protein C resistance	1		1				
Agranulocytosis	33	8	33				
Anaemia	1225	224	715	187	510	4	16
Anaemia folate deficiency	6	1	3	2	3		
Anaemia macrocytic	32	3	20	4	12		
Anaemia megaloblastic	3		2	1	1		
Anaemia neonatal						2	2
Anaemia of chronic disease	1				1		
Anaemia of pregnancy	1			1	1		
Anaemia vitamin B12 deficiency	15	4	7	3	8		
Anisocytosis	9	3	5		4		
Antiphospholipid syndrome	79	36	79				

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aplasia pure red cell	6	1	6				
Aplastic anaemia	49	18	49				
Atypical haemolytic uraemic syndrome	6	3	6				
Autoimmune anaemia	8	1	8				
Autoimmune haemolytic anaemia	129	44	129			1	1
Autoimmune neutropenia	10	3	10				
Autoimmune pancytopenia	1		1				
Bandaemia	1				1		
Basophilia	3				3		
Bicytopenia	22	5	22				
Blood disorder	116	22	55	23	61	1	1
Blood loss anaemia	32	15	32				
Bone marrow disorder	14		10	1	4		
Bone marrow failure	20	8	20				
Bone marrow infiltration	1		1				
Bone marrow oedema	29	5	12	14	17		
Bone marrow oedema syndrome	2	1	1	1	1		
Coagulation disorder neonatal	1		1				
Coagulation factor deficiency	3	1	1	1	2		
Coagulopathy	501	79	297	85	204	1	1
Cold type haemolytic anaemia	7	3	7				
Coombs negative haemolytic anaemia	6		6				
Coombs positive haemolytic anaemia	7	4	7				
Cyclic neutropenia	1			1	1		
Cytopenia	23	10	23				
Deficiency anaemia	2				2		
Dermatopathic lymphadenopathy	1				1		

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Disseminated intravascular coagulation	115	31	115				
Disseminated intravascular coagulation in newborn	2		2				
Dysglobulinaemia	1				1		
Elephantiasis	4	1	4				
Elliptocytosis	2		1		1		
Eosinopenia	2				2		
Eosinophilia	154	21	89	25	65		1
Erythropenia	6	2	5	1	1		
Erythropoiesis abnormal	2	1	2				
Evans syndrome	10	1	10				
Extramedullary haemopoiesis	1				1		
Factor IX inhibition	1	1	1				
Factor VIII inhibition	2		2				
Febrile bone marrow aplasia	3	1	3				
Febrile neutropenia	26	9	26				
Foetal anaemia	1		1				
Granulocytopenia	5	1	5				
Granulocytosis	1				1		
Granulomatous lymphadenitis	2	2	2				
Haemoconcentration	2	1	1		1		
Haemoglobinaemia	3		3				
Haemolysis	73	28	73				
Haemolytic anaemia	88	29	88			2	2
Haemolytic uraemic syndrome	8	2	8				
Haemorrhagic diathesis	90	24	90				
Haemorrhagic disorder	47	13	47				
Heparin-induced thrombocytopenia	15	6	15				

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hilar lymphadenopathy	40	3	13	9	27		
Hyperchromic anaemia	4		3	1	1		
Hypercoagulation	66	13	41	12	25		
Hypereosinophilic syndrome	11	3	11				
Hyperfibrinogenaemia	10		9	1	1		
Hypergammaglobulinaemia	22	2	3	9	19		
Hyperglobulinaemia	3			1	3		
Hyperleukocytosis	152	44	152				
Hyperplasia of thymic epithelium	1				1		
Hyperprothrombinaemia	1		1				
Hypersplenism	1				1		
Hyperviscosity syndrome	1		1				
Hypochromasia	5		1		4		
Hypochromic anaemia	14	5	9	3	5		
Hypocoagulable state	3		2		1		
Hypofibrinogenaemia	2	1	1		1		
Hypoplastic anaemia	2		2				
Hypoprothrombinaemia	1		1				
Hyposplenism	1	1	1				
Idiopathic CD4 lymphocytopenia	1		1				
Idiopathic neutropenia	1		1				
Immune thrombocytopenia	893	245	893			2	6
Increased tendency to bruise	250	19	82	93	168		1
Intravascular haemolysis	2	1	2				
Iron deficiency anaemia	110	16	57	22	53	1	1
Isoimmune haemolytic disease	1		1				
Jaundice acholuric	2		2				

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Leukaemoid reaction	1		1				
Leukocyte vacuolisation	1	1	1				
Leukocytosis	280	45	141	47	139		1
Leukopenia	252	77	252				1
Lupus anticoagulant hypoprothrombinaemia syndrome	1	1	1				
Lymphadenitis	2521	126	433	939	2088		2
Lymphadenocyst	1				1		
Lymphadenopathy	79171	2768	10631	28302	68540	26	80
Lymphadenopathy mediastinal	60	14	31	9	29		
Lymphatic disorder	55	8	18	14	37	1	1
Lymphatic insufficiency	3		2		1		
Lymphatic obstruction	6	2	3	1	3		
Lymph node calcification	1			1	1		
Lymph node fibrosis	2			1	2		
Lymph node haemorrhage	4	1	2		2		
Lymph node pain	9199	517	1999	2451	7200	2	19
Lymph node rupture	1				1		
Lymph node ulcer	1		1				
Lymphocytic infiltration	23	3	12	5	11		
Lymphocytosis	65	12	30	12	35		
Lymphoid tissue hyperplasia	10		5	3	5		
Lymphopenia	299	39	127	47	172	1	2
Macrocytosis	12	4	6	4	6		
Mast cell activation syndrome	90	46	90				1
Mastocytosis	14	2	5	3	9		1
Methaemoglobinaemia	1		1				
Microangiopathic haemolytic anaemia	8	2	7	1	1		

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Microcytic anaemia	46	9	22	11	24		
Microcytosis	7	1	1		6		
Monoclonal B-cell lymphocytosis	3	2	3				
Monocytopenia	5		1		4		
Monocytosis	40	3	15	8	25		1
Myelocytosis	4		1	2	3		
Myelosuppression	17	5	17				
Necrotic lymphadenopathy	11	1	11				
Nephrogenic anaemia	3	2	3				
Neutropenia	258	86	258			1	3
Neutropenia neonatal	1		1				
Neutrophilia	89	10	45	14	44		
Normochromic anaemia	14	5	11	1	3		
Normochromic normocytic anaemia	15	2	6	3	9		
Normocytic anaemia	52	7	29	4	23		
Nucleated red cells	1				1		
Pancytopenia	154	43	154				
Paratracheal lymphadenopathy	13		4	3	9		
Pernicious anaemia	9	3	5	1	4		
Placental transfusion syndrome	2		2				
Plasma cell disorder	1				1		
Platelet anisocytosis	6		4		2		
Platelet destruction increased	1	1	1				
Platelet disorder	53	7	22	11	31		
Platelet dysfunction	3	1	1		2		
Platelet production decreased	1		1				
Poikilocytosis	6	2	2	1	4		

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Polychromasia	7		2	2	5		
Polycythaemia	34	8	16	7	18		
Polycythaemia neonatorum	1		1				
Post-anaphylaxis mast cell anergy	1		1				
Pseudolymphoma	24	2	9	8	15		
Purpura non-thrombocytopenic	16	1	7	2	9		
Red blood cell abnormality	16		4	2	12		1
Reticulocytosis	4		2		2		
Reticuloendothelial dysfunction	1		1				
Retroperitoneal lymphadenopathy	3		2	1	1		
Sarcoidosis of lymph node	1	1	1				
Schistocytosis	1		1				
Secondary thrombocytosis	2	1	2				
Sickle cell anaemia with crisis	27	7	27				
Spherocytic anaemia	1				1		
Spleen atrophy	1		1				
Spleen congestion	2			2	2		
Spleen disorder	26	8	14	5	12		
Spleen ischaemia	3	2	3				
Splenic artery thrombosis	9	3	9				
Splenic cyst	6	1	1		5		
Splenic embolism	1		1				
Splenic granuloma	2	2	2				
Splenic haematoma	1	1	1				
Splenic haemorrhage	3	2	3				
Splenic induration	2	1	2				
Splenic infarction	82	23	82				

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Splenic lesion	6	4	5		1		
Splenic necrosis	1		1				
Splenic thrombosis	7	3	7				
Splenic vein thrombosis	21	5	21				1
Splenitis	5		4		1		
Splenomegaly	206	43	113	44	93		
Spontaneous haematoma	214	19	64	47	150		2
Spontaneous haemorrhage	10	5	10			1	1
Spur cell anaemia	1			1	1		
Stress polycythaemia	1		1				
Thrombocytopenia	2002	485	2002			3	12
Thrombocytopenia neonatal	1	1	1				
Thrombocytopenic purpura	115	17	100	5	15	1	1
Thrombocytosis	109	20	57	26	52		
Thrombosis with thrombocytopenia syndrome	82	35	82				
Thrombotic microangiopathy	35	11	35				
Thrombotic thrombocytopenic purpura	110	30	110				1
Thymus disorder	8	1	3	2	5		
Thymus enlargement	5	2	2		3		
Warm autoimmune haemolytic anaemia	10	5	10				
White blood cell disorder	49	3	15	11	34	1	2
Total:	100970	5679	20806	32583	80164	51	169

System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal precordial movement	1				1		
Accelerated idioventricular rhythm	1	1	1				
Accessory cardiac pathway	1	1	1				
Acquired left ventricle outflow tract obstruction	1		1				
Acute cardiac event	13	3	13				
Acute coronary syndrome	404	141	403	1	1	1	1
Acute left ventricular failure	11	4	11				
Acute myocardial infarction	1135	360	1135			2	2
Acute right ventricular failure	2	1	2				
Adams-Stokes syndrome	3		3				
Angina pectoris	4085	2048	4085			31	44
Angina unstable	72	21	72				1
Aortic valve calcification	6		3		3		
Aortic valve disease	10	3	7	2	3		
Aortic valve disease mixed	2	1	2				
Aortic valve incompetence	87	33	87				
Aortic valve sclerosis	8	2	5	1	3		
Aortic valve stenosis	26	6	22	1	4		
Aortic valve thickening	1		1				
Arrhythmia	9658	5568	9657	1	1	58	93
Arrhythmia neonatal	3	2	3			1	2
Arrhythmia supraventricular	83	25	62	9	21		
Arrhythmic storm	4	1	4				
Arteriosclerosis coronary artery	92	24	81		11		
Arteriospasm coronary	37	15	37				
Arteritis coronary	3	3	3				
Athletic heart syndrome	1			1	1		

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Atrial enlargement	7	2	3	2	4		
Atrial fibrillation	3554	1142	3554			26	43
Atrial flutter	359	79	246	67	113	3	4
Atrial hypertrophy	1			1	1		
Atrial tachycardia	94	18	59	18	35	3	4
Atrial thrombosis	25	5	25				
Atrioventricular block	155	49	130	12	25		2
Atrioventricular block complete	129	35	129			2	3
Atrioventricular block first degree	48	6	28	11	20		
Atrioventricular block second degree	67	18	57	5	10		
Atrioventricular dissociation	2		2				
Autoimmune myocarditis	4		4				
Bezold-Jarisch reflex	1				1		
Bifascicular block	2		2				
Bradyarrhythmia	14	1	10	1	4		
Bradycardia	1295	301	1295			4	12
Bradycardia foetal	7	2	7				
Bradycardia neonatal						2	2
Bundle branch block	17	2	7	1	10		
Bundle branch block bilateral	3		1	1	2		
Bundle branch block left	145	49	96	27	49		1
Bundle branch block right	173	28	96	29	77	1	1
Cardiac amyloidosis	8	4	8				
Cardiac aneurysm	28	8	28				
Cardiac arrest	1516	391	1516			2	6
Cardiac arrest neonatal	1		1				
Cardiac asthma	13	1	13				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cardiac contractility decreased	6	4	5	1	1		
Cardiac discomfort	1241	188	354	563	887	3	4
Cardiac disorder	1570	290	759	356	811	4	10
Cardiac dysfunction	91	28	91				
Cardiac failure	1909	573	1908	1	1	7	11
Cardiac failure acute	249	57	249				1
Cardiac failure chronic	96	37	96				
Cardiac failure congestive	249	70	249				3
Cardiac failure high output	1	1	1				
Cardiac fibrillation	188	78	188			2	3
Cardiac flutter	1196	349	1196			3	10
Cardiac granuloma	1	1	1				
Cardiac hypertrophy	64	17	47	8	17		
Cardiac perforation	3	2	3				
Cardiac perfusion defect	1		1				
Cardiac sarcoidosis	7	3	7				
Cardiac septal hypertrophy	5	1	2	1	3		
Cardiac steatosis	4	3	4				
Cardiac tamponade	108	37	108				
Cardiac valve discolouration	1	1	1				
Cardiac valve disease	56	12	33	13	23		
Cardiac valve sclerosis	3	1	3				
Cardiac ventricular disorder	8	1	3	3	5		
Cardiac ventricular thrombosis	37	9	37				
Cardiogenic shock	229	71	228	1	1		
Cardiomegaly	376	73	235	65	141	2	2
Cardiomyopathy	288	115	287		1	1	1

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cardiomyopathy acute	2		2				
Cardiomyopathy alcoholic	1		1				
Cardiomyopathy neonatal	3	1	3				
Cardiopulmonary failure	80	19	80				
Cardiorenal syndrome	8	4	8				
Cardio-respiratory arrest	757	139	757				
Cardio-respiratory distress	9	3	9			1	1
Cardiovascular deconditioning	19	1	1	15	18		
Cardiovascular disorder	2404	204	618	1001	1786	3	6
Cardiovascular insufficiency	105	48	105				2
Cardiovascular symptom	35	9	24	5	11		
Carditis	178	112	178			1	2
Chordae tendinae rupture	4	3	4				
Chronic coronary syndrome	3	2	3				
Chronic left ventricular failure	1	1	1				
Conduction disorder	25	4	12	7	13		
Congestive cardiomyopathy	142	64	142				
Coronary artery aneurysm	4	2	4				
Coronary artery dilatation	10	3	6	3	4		
Coronary artery disease	261	81	204	29	57	5	5
Coronary artery dissection	25	10	25				
Coronary artery embolism	5	1	5				
Coronary artery insufficiency	3	1	3				
Coronary artery occlusion	106	31	106			1	3
Coronary artery perforation	1		1				
Coronary artery stenosis	108	25	108				
Coronary artery thrombosis	127	35	127				1

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Coronary ostial stenosis	4	2	4				
Cor pulmonale	19	4	19				
Cor pulmonale acute	36	15	36				
Cor pulmonale chronic	2	2	2				
Defect conduction intraventricular	14	2	8	3	6		
Degenerative aortic valve disease	2	1	2				
Degenerative mitral valve disease	1		1				
Diastolic dysfunction	43	7	22	8	21		
Dilatation atrial	16	4	10	2	6		
Dilatation ventricular	18	3	12		6		
Dressler's syndrome	8	1	5	2	3		
Early repolarisation syndrome	2	2	2				
Endocardial disease	1		1				
Endocardial fibrosis	2	1	2				
Endocarditis fibroplastica	1	1	1				
Endocarditis noninfective	1		1				
Endocarditis rheumatic	1	1	1				
Eosinophilic myocarditis	8	4	8				
Extrasystoles	1914	279	747	568	1167	5	8
Foetal arrhythmia	1	1	1				
Foetal cardiac arrest	17	2	17				
Foetal heart rate acceleration abnormality	1		1				
Foetal heart rate deceleration abnormality	1	1	1			1	1
Foetal heart rate disorder	1		1				
Gastrocardiac syndrome	4			1	4		
Giant cell myocarditis	2	2	2				
Haemorrhage coronary artery	3	3	3				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Heart alternation	15	3	5	6	10		
Heart valve calcification	5	1	4		1		
Heart valve incompetence	37	8	22	8	15		
Hepatojugular reflux	8		2	2	6		
Hyperdynamic left ventricle	2		2				
Hyperkinetic heart syndrome	2	2	2				
Hypersensitivity myocarditis	5	2	5				
Hypertensive cardiomyopathy	7	4	7				
Hypertensive heart disease	53	11	39	5	14		
Immune-mediated myocarditis	2	1	2				
Interventricular septum rupture	1		1				
Intracardiac mass	1		1				
Intracardiac thrombus	88	19	88				
Intrapericardial thrombosis	2	1	2				
Ischaemic cardiomyopathy	24	6	24				
Kounis syndrome	4	2	4				
Left atrial dilatation	20	2	9	4	11		
Left atrial enlargement	33	7	15	10	18		
Left ventricular dilatation	25	2	15	6	10		
Left ventricular dysfunction	162	51	122	16	40		
Left ventricular enlargement	9	3	7		2		
Left ventricular failure	87	32	87				2
Left ventricular hypertrophy	108	14	61	19	47		
Long QT syndrome	8	5	8				
Low cardiac output syndrome	8	4	8				
Lupus endocarditis	1	1	1				
Microvascular coronary artery disease	9	6	9				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mitral valve calcification	7		4	1	3		
Mitral valve disease	21	4	12	4	9		
Mitral valve incompetence	235	101	235			6	6
Mitral valve prolapse	45	17	29	7	16		
Mitral valve sclerosis	4	3	4				
Mitral valve stenosis	6		6				
Mitral valve thickening	2		2				
Myocardial calcification	1				1		
Myocardial fibrosis	65	7	49	5	16		
Myocardial haemorrhage	3	2	3				
Myocardial hypoxia	10	5	10				
Myocardial infarction	2741	891	2741			29	38
Myocardial injury	116	46	116				
Myocardial ischaemia	239	71	239				1
Myocardial necrosis	31	9	31				1
Myocardial oedema	57	21	57				
Myocardial rupture	22	4	22				
Myocarditis	10363	4624	10363			15	26
Myocarditis post infection	2	1	2				
Myopericarditis	1792	692	1792			5	10
Nodal arrhythmia	4	1	3		1		
Nodal rhythm	11	1	8	1	3		
Palpitations	30435	4200	10639	8828	19796	30	74
Papillary muscle disorder	1		1				
Papillary muscle haemorrhage	1	1	1				
Papillary muscle rupture	1		1				
Paroxysmal arrhythmia	11	1	7	2	4		

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Paroxysmal atrioventricular block	6		6				
Pericardial cyst	3			1	3		
Pericardial disease	46	13	27	8	19		
Pericardial effusion	1734	706	1734			10	14
Pericardial fibrosis	37	18	37				
Pericardial haemorrhage	42	13	42				
Pericardial mass	3	2	3				
Pericardial rub	29	4	14	9	15		
Pericarditis	9783	4114	9783			20	42
Pericarditis adhesive	1		1				
Pericarditis constrictive	16	5	16				
Pericarditis lupus	1	1	1				
Pericarditis rheumatic	1		1				
Pericarditis uraemic	1		1				
Pleuropericarditis	72	26	72				3
Pneumopericardium	2	1	2				
Positive cardiac inotropic effect	2			2	2		
Postinfarction angina	1		1				
Postural orthostatic tachycardia syndrome	306	72	178	78	128		1
Prinzmetal angina	36	17	36				1
Pulmonary valve disease	2		1		1		
Pulmonary valve incompetence	7	5	7				
Pulmonary valve stenosis	3	1	3				
Pulmonary valve thickening	1		1				
Pulseless electrical activity	40	12	40				
Rebound tachycardia	1				1		
Restrictive cardiomyopathy	2		2				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Rheumatic heart disease	5	4	5				
Rhythm idioventricular	1		1				
Right atrial dilatation	6		4	1	2		
Right atrial enlargement	10	1	3	3	7		
Right atrial hypertrophy	2	1	1	1	1		
Right ventricular diastolic collapse	1		1				
Right ventricular dilatation	27	8	17	2	10		
Right ventricular dysfunction	32	11	27	1	5		
Right ventricular enlargement	6	2	3	1	3		
Right ventricular failure	71	23	71				
Right ventricular hypertrophy	10	4	8	1	2		1
Silent myocardial infarction	6	4	6				
Sinoatrial block	8		8				
Sinus arrest	16	4	16				
Sinus arrhythmia	113	28	63	31	50		
Sinus bradycardia	148	31	88	21	60		1
Sinus node dysfunction	35	18	35				
Sinus tachycardia	849	152	438	162	411	1	2
Stress cardiomyopathy	121	36	106	7	15	1	3
Subendocardial haemorrhage	1		1				
Subendocardial ischaemia	2	1	2				
Supraventricular extrasystoles	296	55	151	50	145	3	3
Supraventricular tachyarrhythmia	8	2	5	1	3		
Supraventricular tachycardia	445	90	303	67	142		2
Systolic dysfunction	28	10	20	5	8		
Tachyarrhythmia	189	38	108	32	81	3	5
Tachycardia	25509	3002	7814	7876	17695	26	70

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tachycardia foetal	11	2	11				1
Tachycardia induced cardiomyopathy	5	3	5				
Tachycardia paroxysmal	80	14	45	12	35		1
Torsade de pointes	14	4	14				
Toxic cardiomyopathy	4	3	4				
Tricuspid valve disease	5	2	5				
Tricuspid valve incompetence	117	44	117				
Tricuspid valve prolapse	1	1	1				
Trifascicular block	5	4	5				
Ventricle rupture	5	2	5				
Ventricular arrhythmia	68	24	68				
Ventricular asystole	1		1				
Ventricular dysfunction	38	8	28	3	10		
Ventricular dyskinesia	6	2	4		2		
Ventricular enlargement	10	5	7		3		
Ventricular extrasystoles	830	154	426	148	404	1	2
Ventricular failure	8	3	8				
Ventricular fibrillation	288	92	288			2	3
Ventricular flutter	4	2	4				
Ventricular hypertrophy	25	2	15	5	10		
Ventricular hypokinesia	127	47	127				
Ventricular pre-excitation	3	2	2	1	1		
Ventricular remodelling	2	1	2				
Ventricular tachyarrhythmia	5	2	5				
Ventricular tachycardia	284	98	284				
Wandering pacemaker	1		1				
Wolff-Parkinson-White syndrome	17	7	17				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Total:	126993	33519	82303	20300	44690	327	608

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aberrant aortic arch	2		2				
Abnormal palmar/plantar creases	1		1				
Accessory muscle	3			1	3		
Accessory spleen	4	1	2	1	2		
Acquired gene mutation	1		1				
Acral peeling skin syndrome	2	1	1		1		
Acrodermatitis enteropathica	1				1		
Adenomatous polyposis coli	2	1	1		1		
Adrenogenital syndrome	1		1				
Adrenoleukodystrophy	1			1	1		
Alpha-1 antitrypsin deficiency	2		1		1		
Amegakaryocytic thrombocytopenia	2		2				
Amyotrophic lateral sclerosis gene carrier	2		2				
Anal atresia	1	1	1				
Anencephaly	7		7				
Ankyloglossia congenital	3	1	3			1	1
Anodontia	1			1	1		
Anomalous pulmonary venous connection	2		2				
Anophthalmos	1		1				
Anotia	1		1				
Antithrombin III deficiency	6	1	5	1	1		

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aorta hypoplasia	1	1	1				
Aplasia	2	1	2				
Aplasia cutis congenita	1		1				
Arachnodactyly	1				1		
Argininosuccinate synthetase deficiency	2			1	2		
Arnold-Chiari malformation	7	1	7				
Arrhythmogenic right ventricular dysplasia	4		4				
Arterial tortuosity syndrome	1			1	1		
Arteriovenous malformation	8	4	8			2	2
ASAH1 related disorder	1		1				
Asplenia	1		1				
Asymmetric crying facies	1			1	1		
Ataxia telangiectasia	2		1	1	1		
Atrial septal defect	40	11	26	9	14	1	1
Atrioventricular septal defect	5	3	5				
Auditory neuropathy spectrum disorder	1	1	1				
Autoimmune lymphoproliferative syndrome	3	2	3				
Benign familial haematuria	1				1		
Benign familial pemphigus	9		1	2	8		
Bicuspid aortic valve	4	1	3	1	1		
Biliary hamartoma	1	1	1				
Birth mark	7		1	2	6		
Blindness congenital	1	1	1				
Block vertebra	5		2	2	3		
Brachydactyly	2	2	2				
Brachyolmia	1		1				
BRAF gene mutation	1	1	1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Brain malformation	2	2	2				
Branchial cyst	4	1	3	1	1		
Breast malformation	1		1				
Brugada syndrome	15	9	15				
CADASIL	1			1	1		
Cancer gene carrier	1				1		
Cardiac septal defect	2	2	2				
Camitine palmitoyltransferase deficiency	1		1				
Cataract congenital	2	1	2				
Caudal regression syndrome	1		1				
Cerebellar hypoplasia	1	1	1				
Cerebral arteriovenous malformation haemorrhagic	1	1	1				
Cerebral cavernous malformation	3	2	3				
Cerebral palsy	17	4	17				
Cerebrovascular arteriovenous malformation	4	3	4				
Chimerism	1				1		
Chordee	2			2	2		
Chronic granulomatous disease	1	1	1				
Cleft lip	2	2	2				
Cleft lip and palate	4	1	4				
Cleft palate	4	3	4				
Cleft uvula	1		1				
Clinodactyly	2		1		1		
Cloacal exstrophy	3	2	3				
Coarctation of the aorta	3		3				
Colour blindness	23	3	13	2	10		
Combined immunodeficiency	2	2	2				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Congenital absence of cranial vault	2		2				
Congenital amputation	1	1	1				
Congenital anomaly	45	16	44	1	1	2	3
Congenital aortic stenosis	1		1				
Congenital arterial malformation	1		1				
Congenital cardiovascular anomaly	1	1	1				
Congenital central nervous system anomaly	6	2	6				
Congenital cerebrovascular anomaly	1		1				
Congenital cystic kidney disease	2		2				1
Congenital cystic lung	3	2	3				
Congenital cytomegalovirus infection	1	1	1				
Congenital diaphragmatic hernia	1	1	1				
Congenital eye disorder	2	1	2				
Congenital foot malformation	1	1	1			1	1
Congenital genital malformation							1
Congenital great vessel anomaly	2		2				
Congenital haematological disorder	1	1	1				
Congenital hand malformation	1	1	1				
Congenital hearing disorder							1
Congenital heart valve disorder	2	1	2				
Congenital hydrocephalus	6	1	6				
Congenital hydronephrosis	3	2	3				
Congenital hypercoagulation	1		1				
Congenital inguinal hernia							1
Congenital jaw malformation	1	1	1				
Congenital LUMBAR syndrome	2	1	2				
Congenital methaemoglobinaemia	1		1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Congenital mitral valve incompetence	1	1	1				
Congenital musculoskeletal disorder	1	1	1				1
Congenital musculoskeletal disorder of limbs	7	4	7				1
Congenital musculoskeletal disorder of skull	2	1	2				
Congenital musculoskeletal disorder of spine	5	1	5				
Congenital myasthenic syndrome	1				1		
Congenital myopathy	1		1				
Congenital neurological degeneration	1	1	1				
Congenital nose malformation	1	1	1				
Congenital nystagmus	1			1	1		
Congenital optic nerve anomaly	1	1	1				
Congenital oral malformation	1	1	1				
Congenital skin dimples	1	1	1				
Congenital thyroid disorder							1
Congenital tricuspid valve atresia	1	1	1				
Corneal dystrophy	7	2	7				
Cortical dysplasia	2	1	2				
Craniosynostosis	2		2				
Cryopyrin associated periodic syndrome	2	1	2				
Cryptorchism	3	2	2		1		
CYP2C19 polymorphism	1				1		
Cystic fibrosis	1				1		
Cystic lymphangioma	7	2	7				
Cytogenetic abnormality	6	2	5	1	1		
Dacryostenosis congenital	2	1	1		1		
Dermoid cyst	7	1	7				
Developmental hip dysplasia	1		1				

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Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Diastematomyelia	1		1				
Diastrophic dysplasia	1		1				
Dolichocolon	1			1	1		
Double inlet left ventricle	1		1				
Double outlet right ventricle	2	2	2				
Ductus arteriosus premature closure	1		1				1
Dysmorphism	6	1	3		3		
Ectopic thyroid	1	1	1				
Ectrodactyly	1	1	1				
Ehlers-Danlos syndrome	20	3	9	7	11		
Elliptocytosis hereditary	1		1				
Encephalocele	3		3				
Epidermolysis bullosa	3	1	3				
Exomphalos	4	3	4				
Factor II mutation	4	1	1	1	3		
Factor IX deficiency	1	1	1				
Factor V deficiency	5	1	3	1	2		
Factor VII deficiency	1	1	1				
Factor VIII deficiency	9	3	8		1		
Factor V Leiden mutation	17	1	6	5	11		
Factor X deficiency	2		1	1	1		
Factor XI deficiency	1		1				
Factor XIII deficiency	1	1	1				
Fallot's tetralogy	7	3	7				
Familial amyotrophic lateral sclerosis	2		2				
Familial hemiplegic migraine	2		2				
Familial mediterranean fever	7	1	3	2	4		

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Congenital, familial and genetic disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Familial periodic paralysis	5	1	3	1	2		
Familial tremor	2		1	1	1		
Fibrodysplasia ossificans progressiva	1	1	1				
Foetal chromosome abnormality	4	3	4				
Foetal cystic hygroma	6	1	6				
Foetal malformation	22	10	22				
Foramen magnum stenosis	1		1				
Friedreich's ataxia	1		1				
Gastrointestinal arteriovenous malformation						1	1
Gastrointestinal malformation	1		1				
Gastroschisis	4	1	4				
Gene mutation	10	1	3	6	7		
Gilbert's syndrome	21	2	8	5	13		
Glucose-6-phosphate dehydrogenase deficiency	4		1		3		
Glycogen storage disease type V	4	2	4				
Glycogen storage disorder	1				1		
Grey matter heterotopia	1	1	1				
Haemophilia	12	3	8	2	4		
Haemorrhagic arteriovenous malformation	1		1				
Hamartoma	2	1	1	1	1		
Heart disease congenital	40	15	40				2
Hereditary angioedema	9	6	8		1		1
Hereditary angioedema with normal C1 esterase inhibitor	1		1				
Hereditary ataxia	3	2	3				
Hereditary fructose intolerance	2			2	2		
Hereditary haemorrhagic telangiectasia	4			2	4		
Hereditary motor and sensory neuropathy	5	2	3		2		

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Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hereditary neuropathy with liability to pressure palsies	3		3				
Hereditary optic atrophy	1		1				
Hereditary spherocytosis	2		1	1	1		
Heterotaxia	2		2				
Homocystinaemia	1			1	1		
Huntington's disease	10	2	7	1	3		
Hydranencephaly	1		1				
Hydrocele	13	2	4	4	9		
Hyperexplexia	3		1		2		
Hyperglycinaemia	3		2		1		
Hyper IgD syndrome	1				1		
Hypertrophic cardiomyopathy	43	17	43				
Hypochondroplasia	1	1	1				
Hypophosphatasia	1	1	1				
Hypoplastic left heart syndrome	4	1	4				
Hypospadias						1	2
Ichthyosis	1	1	1				
Imperforate oesophagus	1		1				
Inborn error of metabolism	1			1	1		
Intestinal atresia	4	3	4			1	1
Intracranial lipoma	1		1				
Isodicentric chromosome 15 syndrome	1	1	1				
Janus kinase 2 mutation	2	1	2				
Kearns-Sayre syndrome	1				1		
Keratosis follicular	4	2	3		1		
Kidney duplex	2		1	1	1		
Kidney malformation	5	3	5				

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Congenital, familial and genetic disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Klippel-Trenaunay syndrome	1		1				
Laryngomalacia	2	1	2				
Left-to-right cardiac shunt	1		1				
Limb hypoplasia congenital	1		1				
Limb reduction defect	2		2				
Long QT syndrome congenital	1		1				
Low set ears	1		1				
Macrocephaly	1		1			1	1
Macroglossia	26	5	26				1
Malformation venous	1		1				
MELAS syndrome	1		1				
Melkersson-Rosenthal syndrome	4	2	4				
Meningocele	1		1				
Meningomyelocele	1	1	1				
Metabolic myopathy	1			1	1		
Methylenetetrahydrofolate reductase gene mutation	6		1	2	5		
Microcephaly	1		1				
Micrognathia	1		1				
Micropenis	4	1	4				
Microphthalmos	1	1	1				
Mitochondrial encephalomyopathy	1		1				
Mitochondrial myopathy	2			2	2		
Mitral valve atresia	2		2				
Moebius II syndrome	1		1				
Multiple congenital abnormalities	3	2	3				
Muscular dystrophy	9	1	2	4	7		
Myocardial bridging	3	1	3				

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Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Myoclonic dystonia	4	1	4				
Myoclonic epilepsy and ragged-red fibres	1				1		
Myotonic dystrophy	2		1	1	1		
Naevus flammeus	3		1	2	2		
Nail aplasia	1		1				
Neonatal alloimmune thrombocytopenia	1		1				
Neonatal haemochromatosis	1		1				
Neurofibromatosis	5	1	3	1	2		
Non-compaction cardiomyopathy	2	2	2				
Odontogenic cyst	1			1	1		
Osteogenesis imperfecta	2	1	2				
Pachyonychia congenita	1	1	1				
Pancreas divisum	1				1		
Parkes-Weber syndrome	1				1		
Paroxysmal extreme pain disorder	4		2	2	2		
Patent ductus arteriosus						2	2
Pectus excavatum	2	1	1	1	1		
Penoscrotal fusion	1	1	1				
Persistent foetal circulation	1	1	1				
Pfeiffer syndrome	1				1		
Phelan-McDermid syndrome	1		1				
Phimosis	6	1	3	3	3		
Platybasia	1		1				
Polycystic liver disease	1	1	1				
Polydactyly	2	1	1		1		
Polymicrogyria	1		1				
Porencephaly	1		1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Porokeratosis	1		1				
Porphyria	4	1	4				
Porphyria acute	5	2	5				1
Porphyria non-acute	3	2	3				
Potter's syndrome	1	1	1				
Preauricular cyst	2		1		1		
Primary ciliary dyskinesia	1			1	1		
Protein C deficiency	3		1	2	2		
Protein S deficiency	5	3	5				
PTEN gene mutation	1		1				
Pulmonary artery stenosis congenital	1	1	1				
Pulmonary hypoplasia	2		2				
Pulmonary malformation	2	1	2			1	1
Pulmonary sequestration	2	2	2				
Pulmonary valve stenosis congenital	2	2	2			1	1
Rathke's cleft cyst	2	1	1	1	1		
Renal aplasia	2	2	2				
Renal dysplasia	1		1			1	2
Renal fusion anomaly	1	1	1				
Retinitis pigmentosa	6	1	6				
Right-to-left cardiac shunt	1		1				
Rippling muscle disease	1				1		
RUNX1 gene mutation	1	1	1				
Schizencephaly	1		1				
Scimitar syndrome	1		1				
Sensory neuropathy hereditary	2	1	2				
Short-chain acyl-coenzyme A dehydrogenase deficiency	1		1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sickle cell anaemia	2		1	1	1		
Sickle cell disease	2	1	1		1		
Single atrium	1		1				
Single umbilical artery	5	1	4	1	1		
Skeletal dysplasia	1	1	1				
Skin malformation	2		2				
Spina bifida	6	2	6				
Spinal muscular atrophy	2	2	2				
Spinal vessel congenital anomaly	1		1				
Stargardt's disease	1			1	1		
Sturge-Weber syndrome	1		1				
Supernumerary nipple	3		1		2		
Syndactyly	4	1	4				
Syringomyelia	9	4	9				
Talipes	2		2				
Telangiectasia congenital	1		1				
Thalassaemia	1	1	1				
Thalassaemia minor	7	1	2	2	5		
Thyroglossal cyst	4		3	1	1		
Tourette's disorder	21	8	21				
Tracheo-oesophageal fistula	1		1				
Transposition of the great vessels	4	1	4				
Trisomy 13	2	1	2				
Trisomy 16	1	1	1				
Trisomy 18	4	1	4				
Trisomy 21	11	3	11				
Trisomy 8	1	1	1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Turner's syndrome	3	1	1	1	2		
Type IIa hyperlipidaemia	2		1		1		
Type V hyperlipidaemia	7		3		4		
Univentricular heart	1	1	1				
Urachal abnormality	1	1	1				
Urethral atresia	1		1				
Urethral valves	3	2	3				
Urinary tract malformation							1
VACTERL syndrome	1	1	1				
Vascular endothelial growth factor overexpression	1			1	1		
Vascular malformation	6	1	2	3	4		
Venous angioma of brain	4	1	4				
Ventricular hypoplasia	2		2				
Ventricular septal defect	14	6	14			1	1
Vertebral artery hypoplasia	1		1				
Vestibulocerebellar syndrome	3		2		1		
VEXAS syndrome	1	1	1				
Von Willebrand's disease	5	2	5				
Williams syndrome	1		1				
Wolf-Hirschhorn syndrome	1		1				
X-linked lymphoproliferative syndrome	1	1	1				
XXX syndrome	1		1				
Total:	1143	345	904	116	239	17	34

System Organ Class

Ear and labyrinth disorders

Spontaneous		Non Interventional Study
Serious	Nonserious	Serious

* I=Interval, C=Cumulative
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System Organ Class

Ear and labyrinth disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute vestibular syndrome	80	20	51	8	29		
Auditory disorder	238	20	62	79	176		
Aural polyp	1	1	1				
Auricular swelling	42	1	11	10	31		
Autoimmune inner ear disease	2	1	2				
Autophony	4		2	1	2		
Cerumen impaction	10		1	3	9		
Chondrodermatitis nodularis chronica helicis	1		1				
Conductive deafness	9	2	9				
Deafness	1448	484	1448			5	11
Deafness bilateral	99	27	99				
Deafness neurosensory	220	65	220				
Deafness permanent	2	2	2			1	1
Deafness transitory	68	21	68				
Deafness unilateral	719	222	719			2	4
Diplacusis	10		4	2	6		
Dysacusis	25	2	9	5	16		
Ear canal erythema	11	1	3		8		
Ear canal stenosis	3	1	1	2	2		
Ear congestion	219	11	52	54	167		
Ear deformity acquired	3				3		
Ear discomfort	2217	135	508	508	1709	1	1
Ear disorder	286	24	88	53	198	1	1
Ear haemorrhage	90	11	29	22	61		
Ear inflammation	61	15	20	32	41		
Ear odour	1				1		
Ear pain	5188	336	1454	1084	3734	3	11

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System Organ Class

Ear and labyrinth disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ear pruritus	242	7	51	32	191		1
Ear swelling	388	20	103	81	285		1
Endolymphatic hydrops	19	8	19				
Eustachian tube disorder	13	1	9	2	4		
Eustachian tube dysfunction	35	7	12	6	23		
Eustachian tube obstruction	32	5	9	6	23		
Eustachian tube patulous	2				2		
Excessive cerumen production	42	3	13	7	29		1
External ear disorder	5		4	1	1		
External ear inflammation	16		6	3	10		
External ear pain	42	2	13	6	29		
Haematotympanum	1		1				
Hyperacusis	847	105	301	210	546		1
Hypoacusis	2096	255	772	490	1324	2	4
Inner ear disorder	85	10	37	15	48		
Inner ear infarction	8	3	8				
Inner ear inflammation	40	3	19	7	21		
Mastoid disorder	5		1	1	4		
Mastoid effusion	1				1		
Meniere's disease	193	53	193				
Middle ear disorder	6	1	3	2	3		
Middle ear effusion	36	3	9	11	27		1
Middle ear inflammation	36	5	7	20	29		
Misophonia	12		3	2	9		
Mixed deafness	4	2	4				
Motion sickness	203	18	86	25	117		1
Neonatal deafness	1	1	1				

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System Organ Class

Ear and labyrinth disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neurosensory hypoacusis	38	6	27	4	11	1	2
Noninfective myringitis	5			3	5		
Otolithiasis	22		8	8	14		
Otorrhoea	56	7	16	13	40		
Otosclerosis	8	3	6	1	2		
Ototoxicity	5	4	5				
Paraesthesia ear	41	1	12	8	29		
Phobic postural vertigo	17	4	5	6	12		
Presbyacusis	9	2	3	5	6		
Red ear syndrome	10		1	1	9		
Sudden hearing loss	882	363	882			7	8
Superior semicircular canal dehiscence	1		1				
Tinnitus	15833	1522	4286	4532	11547	11	30
Tympanic membrane disorder	28	4	8	4	20		
Tympanic membrane hyperaemia	5	2	3	1	2		
Tympanic membrane perforation	27	5	13	8	14		
Vertigo	13698	964	3909	2713	9789	18	56
Vertigo labyrinthine	23	7	17	1	6		
Vertigo positional	650	79	259	152	391	3	5
Vestibular ataxia	6	2	6				
Vestibular disorder	203	36	103	34	100	1	1
Vestibular ischaemia	3	1	3				
Vestibular paroxysmia	1		1				
Total:	47038	4926	16122	10284	30916	56	141

System Organ Class

Endocrine disorders

Spontaneous	Non Interventional Study

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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Addison's disease	10	7	10				
Adrenal atrophy	1			1	1		
Adrenal cortex necrosis	2		2				
Adrenal disorder	26	5	11	5	15		
Adrenal haemorrhage	10	2	10				
Adrenal insufficiency	55	21	55				
Adrenal mass	9	1	1	4	8		
Adrenal thrombosis	1		1				
Adrenocortical insufficiency acute	56	16	56				
Adrenocorticotropic hormone deficiency	1		1				
Adrenomegaly	7		1	1	6		
Androgen deficiency	2				2		
Anovulatory cycle	294	29	69	127	225		
Autoimmune hypothyroidism	8	6	8				
Autoimmune thyroid disorder	14	8	14				
Autoimmune thyroiditis	336	194	336			4	4
Basedow's disease	418	221	418			1	2
Carcinoid crisis	1	1	1				
Central hypothyroidism	2	1	2				
Cushingoid	8	1	3	1	5		
Cushing's syndrome	4	1	4				
Delayed menarche	7	2	2		5		
Diabetes insipidus	29	20	29				
Empty sella syndrome	2	2	2				
Endocrine disorder	53	4	21	17	32	1	1
Euthyroid sick syndrome	2				2		
Fertility increased	3			3	3		

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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glucocorticoid deficiency	3	2	3				
Goitre	232	29	88	64	144		
Growth hormone deficiency	2	1	2				
Haemorrhagic thyroid cyst	2			1	2		
Hyperadrenocorticism	1	1	1				
Hyperaldosteronism	2		2				
Hypercalcaemia of malignancy	1				1		
Hyperoestrogenism	1				1		
Hyperparathyroidism	8		3	1	5		
Hyperparathyroidism primary	5	1	4		1		
Hyperparathyroidism secondary	2	1	2				
Hyperplasia adrenal	3	3	3				
Hyperprolactinaemia	5	4	5				
Hyperthyroidism	546	245	546			3	7
Hypoparathyroidism	2		1		1		
Hypophysitis	5		2	2	3		
Hypopituitarism	14	1	6	6	8		
Hypothalamo-pituitary disorder	13	9	13				
Hypothyroidic goitre	2			1	2		
Hypothyroidism	433	220	433			2	4
Immune-mediated hypothyroidism	1		1				
Immune-mediated thyroiditis	3	2	3				
Inappropriate antidiuretic hormone secretion	23	9	23				
Luteal phase deficiency	6		1	4	5		
Lymphocytic hypophysitis	1			1	1		
Myxoedema	5	3	5				
Oestrogen deficiency	4		1	3	3		

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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ovarian dysfunction	1				1		
Ovulation delayed	196	4	25	81	171		
Parathyroid disorder	3	1	1	1	2		
Pituitary apoplexy	6	4	6				
Pituitary-dependent Cushing's syndrome	2	1	2				
Pituitary enlargement	2	1	1	1	1		
Pituitary haemorrhage	3		3				
Pituitary infarction	1		1				
Polyglandular autoimmune syndrome type I	1		1				
Polyglandular autoimmune syndrome type II	1		1				
Precocious puberty	2			2	2		
Premature menarche	27		4	3	23		
Primary hyperaldosteronism	3		1	1	2		
Primary hyperthyroidism	6	4	6				
Secondary adrenocortical insufficiency	4		3	1	1		
Secondary hyperthyroidism	2	2	2				
Secondary hypogonadism	1		1				
Silent thyroiditis	9	3	7	1	2		
Thyroid calcification	1				1		
Thyroid cyst	28	4	10	8	18		
Thyroid dermatopathy	1		1				
Thyroid disorder	299	40	82	120	217	3	3
Thyroid haemorrhage	1		1				
Thyroiditis	225	44	102	52	123	2	2
Thyroiditis acute	53	15	53			1	2
Thyroiditis chronic	3	1	1		2		
Thyroiditis subacute	286	65	143	59	143		

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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thyroid mass	123	19	45	41	78		
Thyroid pain	92	7	21	35	71		
Thyroid stimulating hormone deficiency	3			1	3		
Thyrotoxic crisis	34	15	34				
Thyrotoxic periodic paralysis	1			1	1		
Toxic goitre	3	2	3				
Toxic nodular goitre	6	5	6				
Total:	4115	1310	2772	650	1343	17	25

System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal sensation in eye	219	6	52	38	167		
Accommodation disorder	65	6	15	19	50		
Acute macular neuroretinopathy	18	9	18				
Age-related macular degeneration	13	6	13				
Altered visual depth perception	22		5	4	17		
Amaurosis	29	5	29				
Amaurosis fugax	101	42	101			1	1
Amblyopia	11		4	2	7		
Anaesthesia eye	1			1	1		
Angle closure glaucoma	17	6	17				
Anisocoria	90	19	54	17	36		
Anisometropia	1				1		
Anterior chamber cell	1		1				
Anterior chamber flare	2		1	1	1		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anterior chamber inflammation	3	2	3				
Anterior chamber opacity	1				1		
Anterior segment ischaemia	1	1	1				
Arteriosclerotic retinopathy	3	1	3				
Asthenopia	676	43	219	99	457		3
Astigmatism	32	5	8	11	24		
Atopic keratoconjunctivitis	1		1				
Autoimmune eye disorder	3	1	2	1	1		
Autoimmune uveitis	6	4	6				
Bell's phenomenon	5	1	3	1	2		
Binocular eye movement disorder	15		8	5	7		
Birdshot chorioretinopathy	2		2				
Blepharal pigmentation	1			1	1		
Blepharitis	195	13	41	57	154		
Blepharitis allergic	2	1	1		1		
Blepharochalasis	3			2	3		
Blepharophimosis	1				1		
Blepharospasm	784	46	158	230	626		1
Blindness	970	318	970			2	4
Blindness cortical	5		5				
Blindness transient	274	91	274			1	1
Blindness unilateral	328	103	328			1	1
Cataract	150	72	150			12	19
Cataract cortical	1		1				
Cataract nuclear	4	1	4				
Cataract subcapsular	3	1	1	1	2		
Central serous chorioretinopathy	46	25	46				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Central vision loss	13	4	13				
Chalazion	55	2	11	14	44		
Charles Bonnet syndrome	3		2		1		
Chloropsia	3	1	3				
Chorioretinal disorder	4		2	1	2		
Chorioretinal folds	1	1	1				
Chorioretinopathy	30	14	29		1		
Choroidal detachment	2	2	2				
Choroidal effusion	4		4				
Choroidal haemorrhage	1	1	1				
Choroidal infarction	1	1	1				
Choroidal neovascularisation	10	4	10				
Choroidal rupture	2		2				
Choroiditis	7	2	7				
Chromatopsia	29	4	9	7	20		
Ciliary muscle spasm	3			1	3		
Cogan's syndrome	2	2	2				
Colour blindness acquired	2	2	2				
Computer vision syndrome	2				2		
Conjunctival adhesion	2		2				
Conjunctival cyst	3			1	3		
Conjunctival defect	1				1		
Conjunctival discolouration	3			1	3		
Conjunctival disorder	12	1	3	3	9		
Conjunctival haemorrhage	437	104	437				5
Conjunctival hyperaemia	222	12	89	27	133		1
Conjunctival irritation	28	1	6	4	22		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Conjunctival oedema	35	2	14	6	21		
Conjunctival pallor	6		2	2	4		
Conjunctival suffusion	1	1	1				
Conjunctival telangiectasia	1				1		
Conjunctival ulcer	2	2	2				
Conjunctival vascular disorder	1		1				
Conjunctivitis allergic	60	5	12	17	48		
Contact lens intolerance	1			1	1		
Corneal bleeding	11	5	11				
Corneal decompensation	1	1	1				
Corneal defect	1		1				
Corneal degeneration	2		2				
Corneal deposits	2			1	2		
Corneal disorder	24	8	16	3	8		
Corneal endothelial cell loss	1	1	1				
Corneal endotheliitis	3	2	3				
Corneal epithelium defect	2	2	2				
Corneal erosion	11	1	5	3	6		
Corneal exfoliation	1		1				
Corneal infiltrates	3		2		1		
Corneal irritation	1			1	1		
Corneal lesion	5		1	3	4		
Corneal oedema	11	2	5	3	6		
Corneal opacity	13	2	13			1	1
Corneal perforation	1	1	1				
Corneal pigmentation	1			1	1		
Corneal scar	1		1				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Comeal thinning	1		1				
Cyanopsia	12	2	6	2	6		
Cyclitis	1	1	1				
Cystoid macular oedema	19	7	19				
Dacryoadenitis acquired	7	3	4	1	3		
Dacryostenosis acquired	6		1	1	5		
Dark circles under eyes	54	5	12	15	42		
Delayed dark adaptation	1			1	1		
Dellen	1				1		
Dermatochalasis	12	2	6	4	6		
Detached Descemet's membrane	1		1				
Detachment of retinal pigment epithelium	2		2				
Diabetic eye disease	1				1		
Diabetic retinal oedema	1				1		
Diabetic retinopathy	2		2				
Diplopia	1722	268	879	278	843	3	4
Disorder of orbit	3	1	1	2	2		
Dry age-related macular degeneration	6	2	6				1
Dry eye	958	67	245	234	713	3	6
Dyschromatopsia	57	10	32	7	25		
Dysmetropsia	2			1	2		
Ectropion	4		3	1	1		
Eczema eyelids	53	3	8	18	45		
Endocrine ophthalmopathy	35	21	35			1	2
Enophthalmos	1	1	1				
Epiretinal membrane	7	4	6	1	1		
Episcleritis	68	4	21	15	47		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Erythema of eyelid	229	10	74	36	155	1	2
Erythropsia	8		2	2	6		
Excessive eye blinking	29	1	9	7	20		
Excessive ocular convergence	1		1				
Exfoliation syndrome	1				1		
Exophthalmos	50	20	50				
Exposure keratitis	2			1	2		
Extraocular muscle disorder	20		12	1	8		
Exudative retinopathy	1	1	1				
Eye allergy	76	7	23	16	53		
Eye colour change	24	2	10	3	14		
Eye discharge	218	12	62	39	156		
Eye disorder	855	69	283	169	572	2	7
Eye haematoma	65	17	65				
Eye haemorrhage	566	175	565	1	1	3	8
Eye infarction	50	20	50			1	1
Eye inflammation	571	47	125	171	446	1	3
Eye irritation	1531	71	262	263	1269		3
Eyelash changes	2		1		1		
Eyelash discolouration	6		1	2	5		
Eyelid bleeding	11	2	5	3	6		
Eyelid cyst	16	1	8	3	8		
Eyelid disorder	111	8	44	18	67		1
Eyelid exfoliation	10		2	1	8		
Eyelid function disorder	97	7	47	13	50		
Eyelid haematoma	50	5	13	6	37		
Eyelid irritation	124	7	25	28	99		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Eyelid margin crusting	19	1	3	2	16		
Eyelid myoclonus	10	3	10				
Eyelid myokymia	23	3	8	6	15		
Eyelid oedema	1004	43	275	187	729	1	4
Eyelid pain	166	6	35	31	131		1
Eyelid ptosis	485	76	246	66	239		2
Eyelid rash	76	8	25	13	51		
Eyelid retraction	6		3		3		
Eyelid sensory disorder	35	2	8	6	27		
Eyelid skin dryness	18		3	5	15		
Eyelids pruritus	149	2	38	17	111		
Eyelid thickening	14		3	4	11		
Eyelid vascular disorder	4	1	1		3		
Eye movement disorder	353	49	201	57	152		1
Eye oedema	228	13	68	40	160		2
Eye opacity	2			1	2		
Eye pain	6217	447	1821	1288	4396	2	17
Eye paraesthesia	57	2	21	7	36		
Eye pruritus	1680	60	392	281	1288	4	7
Eye swelling	2929	185	866	622	2063	2	6
Eye symptom	28	5	11	4	17		
Eye ulcer	15	3	8	3	7		
Floppy eyelid syndrome	2		2				
Foreign body sensation in eyes	124	13	35	31	89		
Fuchs' syndrome	4	1	4				1
Gaze palsy	99	27	98		1		
Giant papillary conjunctivitis	3		1		2		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glare	33	3	9		24		
Glaucoma	107	38	107			6	10
Glaucomatocyclitic crises	2		2				
Growth of eyelashes	1		1				
Halo vision	35	4	16	3	19		
Heteronymous diplopia	1		1				
Heterophoria	10	2	5	2	5		
Holmes-Adie pupil	8	1	2	5	6		
Homonymous diplopia	4	2	4				
Hyperaesthesia eye	6	1	2		4		
Hypermetropia	27	5	10	8	17		
Hypoaesthesia eye	128	15	49	18	79		
Hypotony of eye							1
Idiopathic orbital inflammation	5	2	5				
Inflammation of lacrimal passage	2	1	1	1	1		
Iridocele	1	1	1				
Iridocyclitis	161	62	161				1
Iris adhesions	4	3	4				
Iris cyst	1			1	1		
Iris discolouration	2			1	2		
Iris disorder	6		1	4	5		
Iris neovascularisation	1	1	1				
Iritis	119	22	52	34	67	2	2
Keratic precipitates	5	1	5				
Keratitis	86	13	37	18	49		
Keratitis interstitial	1	1	1				
Keratoconus	5	2	5			1	1

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lacrimal disorder	12	1	2	4	10		
Lacrimal gland enlargement	5	1	2	1	3		
Lacrimal structural disorder	1		1				
Lacrimation decreased	16	4	10	4	6		
Lacrimation disorder	13		2	2	11		
Lacrimation increased	1555	85	341	326	1214	1	7
Lagophthalmos	43	7	26	4	17	1	1
Lens dislocation	1		1				
Lens disorder	4			3	4		
Lenticular opacities	4	1	4				
Lid margin discharge	1				1		
Lid sulcus deepened	12	5	7	2	5		
Limbal swelling	4		3		1		
Loss of visual contrast sensitivity	2		1		1		
Macular cherry-red spots	2	2	2				
Macular degeneration	54	14	54			2	3
Macular detachment	4	3	4				
Macular fibrosis	2		2				
Macular hole	13	5	13				2
Macular ischaemia	3	2	3				
Macular oedema	112	42	112				1
Macular opacity	1	1	1				
Macular rupture	2		2				
Macular scar	1				1		
Maculopathy	35	5	25	4	10		
Meibomian gland discharge	1				1		
Meibomian gland dysfunction	8		2	4	6		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Meibomianitis	2	1	1	1	1		
Metamorphopsia	90	12	51	12	39		
Miosis	57	5	22	9	35		
Mydriasis	246	20	100	31	146		
Myopia	61	10	21	19	40		
Myopic chorioretinal degeneration	1		1				
Necrotising retinitis	11	6	11				
Necrotising scleritis	1		1				
Neovascular age-related macular degeneration	24	12	24				
Neurological eyelid disorder	5		1	3	4		
Night blindness	16	1	2	6	14		
Noninfective chorioretinitis	2	1	2				
Noninfective conjunctivitis	2				2		
Ocular discomfort	1349	85	257	418	1092		
Ocular dysmetria	2		1		1		
Ocular hyperaemia	2176	104	522	416	1654	4	9
Ocular hypertension	74	39	74			1	1
Ocular ischaemic syndrome	7	3	7				
Ocular myasthenia	31	13	31				
Ocular rosacea	8	2	2	2	6		
Ocular sarcoidosis	2		2				
Ocular vascular disorder	106	23	85	3	21		
Ocular vasculitis	9	6	9				
Oculogyric crisis	17	6	17				1
Open angle glaucoma	4	1	4				
Ophthalmic artery aneurysm	1		1				
Ophthalmic artery occlusion	5	5	5				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ophthalmic artery thrombosis	13	4	13				
Ophthalmic vein thrombosis	151	73	151			1	1
Ophthalmoplegia	125	43	125			1	1
Opsoclonus myoclonus	3	2	3				
Optic atrophy	13	6	13				
Optic disc disorder	7		3	3	4		
Optic disc haemorrhage	7	2	7				
Optic discs blurred	1		1				
Optic ischaemic neuropathy	150	47	150				
Optic nerve compression	1	1	1				
Optic nerve disorder	45	9	27	8	18		1
Optic nerve infarction	11	3	11				
Optic nerve sheath haemorrhage	1		1				
Optic neuropathy	34	12	34				
Orbital cyst	4	1	3		1		
Orbital haematoma	5		5				
Orbital haemorrhage	2		2				
Orbital myositis	5	3	5				
Orbital oedema	12	4	11	1	1		
Orbital swelling	12	1	2	3	10		
Oscillopsia	12	2	5	3	7		
Panophthalmitis	3	1	3				
Papilloedema	152	68	152				
Papillophlebitis	3	1	3				
Paralytic lagophthalmos	6	1	6				
Parophthalmia	6		2	4	4		
Periorbital discomfort	17		3	3	14		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Periorbital disorder	6				6		
Periorbital fat herniation	1			1	1		
Periorbital inflammation	3		1	1	2		
Periorbital irritation	2				2		
Periorbital oedema	301	36	124	66	177		4
Periorbital pain	56	9	24	11	32		1
Periorbital swelling	890	40	215	218	675		
Photokeratitis	1	1	1				
Photophobia	2800	194	949	547	1851	3	5
Photopsia	814	68	302	160	512		1
Pigmentary glaucoma	2		2				
Pinguecula	2	1	1		1		
Posterior capsule opacification	3	2	3				
Presbyopia	12	1	3	2	9		
Pseudomyopia	3		1	1	2		
Pseudopapilloedema	1			1	1		
Pterygium	4		1	1	3		
Punctate keratitis	12	4	12				
Pupil fixed	23	5	23				
Pupillary deformity	2		2				
Pupillary disorder	19	2	7	3	12		
Pupillary reflex impaired	34	4	21	5	13		
Recession of chamber angle of eye	1		1				
Refraction disorder	5	1	2	2	3		
Retinal aneurysm	7	3	7				
Retinal artery embolism	15	6	15				
Retinal artery occlusion	207	52	207				2

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Retinal artery stenosis	2	2	2				
Retinal artery thrombosis	32	5	29	1	3		
Retinal cyst	2	1	2				
Retinal degeneration	19	6	19				
Retinal depigmentation	1		1				
Retinal detachment	204	82	204			3	4
Retinal disorder	29	3	13	5	16		
Retinal drusen	3	1	3				
Retinal dystrophy	2		2				
Retinal exudates	16	7	15	1	1		
Retinal fibrosis	1		1				
Retinal fovea disorder	2		2				
Retinal haemorrhage	142	55	142			1	2
Retinal infarction	11	4	11				
Retinal ischaemia	18	8	18			1	1
Retinal microangiopathy	2	2	2				
Retinal neovascularisation	3	2	3				
Retinal oedema	26	11	26				
Retinal pigmentation	2		1	1	1		
Retinal pigment epitheliopathy	7	1	7				
Retinal scar	2		1		1		
Retinal tear	86	38	86				2
Retinal toxicity	3		3				
Retinal vascular disorder	17	9	17				
Retinal vascular occlusion	38	19	38				
Retinal vascular thrombosis	91	21	80	5	11		1
Retinal vasculitis	17	10	17				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Retinal vein occlusion	416	123	416			4	4
Retinal vein thrombosis	155	49	141	5	14		1
Retinal vein varices	1				1		
Retinal vessel avulsion	1		1				
Retinal white dots syndrome	12	10	12				
Retinopathy	21	5	21				
Retinopathy hypertensive	6	2	6				
Retinoschisis	3	1	3				
Rhegmatogenous retinal detachment	2	1	2				
Saccadic eye movement	5	1	1	3	4		
Scintillating scotoma	58	5	20	7	38		
Scleral cyst	4		1	1	3		
Scleral discolouration	14		4	2	10		
Scleral disorder	6		3	1	3		
Scleral haemorrhage	10		6	1	4		
Scleral hyperaemia	5	1	1	1	4		
Scleral oedema	3	3	3				
Scleral pigmentation	1			1	1		
Scleritis	51	13	51				
Serous retinal detachment	7	6	7				
Spontaneous hyphaema	2		2				
Staphyloma	1		1				
Strabismus	95	12	48	12	47		
Subretinal fluid	4	1	4				
Subretinal haematoma	2	1	2				
Sudden visual loss	36	11	36				
Swelling of eyelid	1307	47	278	297	1029		3

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Swollen tear duct	5		1		4		
Symblepharon	1		1				
Sympathetic ophthalmia	1		1				
Tear discolouration	1			1	1		
Tolosa-Hunt syndrome	7	3	7				
Tractional retinal detachment	1	1	1				
Ulcerative keratitis	23	11	23				
Uveitis	346	137	346			5	9
Venous stasis retinopathy	4		4				
Vision blurred	8600	894	3015	1659	5585	7	24
Visual acuity reduced	602	75	276	158	326		1
Visual acuity reduced transiently	18		2	7	16		
Visual brightness	29	1	12		17		
Visual field defect	632	104	331	115	301	1	3
Visual impairment	7540	846	2556	2238	4984	7	22
Visual snow syndrome	27	3	17	6	10		
Vitreoretinal traction syndrome	3	1	3				
Vitreous adhesions	5	4	4	1	1		
Vitreous degeneration	5	2	5				
Vitreous detachment	229	81	229			1	2
Vitreous disorder	24	2	11	6	13		
Vitreous floaters	527	54	197	97	330	1	1
Vitreous haematoma	1		1				
Vitreous haemorrhage	94	41	94				
Vitreous haze	10	6	10				
Vitreous opacities	30	6	9	18	21		
Vitreous prolapse	1	1	1				

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System Organ Class

Eye disorders

		Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
Preferred Term	*Total # of Spontaneous AE*	I	C	I	C	I	C
Vitritis	5	2	5				
Vogt-Koyanagi-Harada disease	15	7	15				
Xanthopsia	7		3	2	4		
Xerophthalmia	11	4	11				
Total:	61518	7145	24527	11690	36991	96	252

System Organ Class

Gastrointestinal disorders

		Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
Preferred Term	*Total # of Spontaneous AE*	I	C	I	C	I	C
Abdominal adhesions	7	2	6		1		
Abdominal discomfort	5454	235	1069	1212	4385	7	20
Abdominal distension	2791	194	805	600	1986	7	15
Abdominal fat apron	1				1		
Abdominal hernia	11	2	7		4		1
Abdominal incarcerated hernia	2		2				
Abdominal mass	27	2	9	3	18		
Abdominal migraine	4		1	1	3		
Abdominal pain	19593	1186	4277	4506	15316	19	57
Abdominal pain lower	2345	117	447	943	1898	5	7
Abdominal pain upper	11491	808	3595	2273	7896	22	57
Abdominal rebound tenderness	1	1	1				
Abdominal rigidity	121	10	44	22	77		1
Abdominal symptom	42	3	16	10	26		
Abdominal tenderness	129	15	57	19	72	1	1
Abdominal wall cyst	1		1				
Abdominal wall disorder	1			1	1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal wall haematoma	11	2	9		2		
Abdominal wall haemorrhage	3		3				
Abdominal wall oedema	4	1	2	1	2		
Abnormal faeces	858	25	88	211	770		
Acetonaemic vomiting	11	3	3	4	8		
Achlorhydria	2	1	1		1		
Acid peptic disease	1			1	1		
Acquired macroglossia	2		1		1		
Acquired oesophageal web	1				1		
Acute abdomen	39	7	39			1	1
Acute haemorrhagic ulcerative colitis	5	1	5				
Aerophagia	20	1	6	4	14		
Alcoholic pancreatitis	1		1				
Allergic gastroenteritis	6		2	1	4		
Allergic stomatitis	1				1		
Anaesthesia oral	109	2	18	23	91		
Anal blister	1				1		
Anal eczema	4	1	1	3	3		
Anal erosion	2			1	2		
Anal erythema	3		2		1		
Anal fissure	17		5	6	12		
Anal fistula	7	2	3	1	4		
Anal haemorrhage	83	9	35	20	48		
Anal hypoaesthesia	5	2	4		1		
Anal incontinence	194	20	94	26	100		1
Anal inflammation	5		1	2	4		
Anal paraesthesia	2	2	2				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anal pruritus	28	3	6	10	22		
Anal rash	4	1	2		2		
Anal skin tags	1				1		
Anal spasm	2			1	2		
Anal sphincter atony	27	4	15	4	12		
Anal sphincter hypertonia	1				1		
Anal ulcer	4	2	4				
Anastomotic ulcer perforation	1		1				
Angina bullosa haemorrhagica	8	2	8				
Angular cheilitis	36	2	5	10	31		
Anorectal discomfort	31	3	7	5	24		
Anorectal disorder	23	3	17	5	6		
Anorectal swelling	4		2	2	2		
Aphthous ulcer	915	33	136	213	779	1	5
Apical granuloma	2			1	2		
Appendicitis noninfective	1	1	1				1
Appendicolith	2	1	1		1		
Appendix disorder	16	3	13	1	3	2	3
Aptyalism	75	8	26	19	49		
Ascites	156	61	156				
Atrophic glossitis	5		1	2	4		
Autoimmune colitis	6		6				
Autoimmune enteropathy	1		1				
Autoimmune pancreatitis	18	7	18				
Barrett's oesophagus	9	4	9				1
Bezoar	1				1		
Bile acid malabsorption	9	4	6	1	3		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bowel movement irregularity	152	7	31	23	121	1	2
Breath odour	75	6	26	13	49		1
Brunner's gland hyperplasia	1		1				
Burning mouth syndrome	40	7	12	7	28		
Cardiospasm	23	5	9	4	14		
Change of bowel habit	61	12	25	15	36		
Chapped lips	115	11	26	22	89		
Cheilitis	188	8	37	39	151	1	1
Cheilosis	1			1	1		
Chronic gastritis	43	9	24	13	19		1
Coating in mouth	18	1	5	6	13		
Coeliac artery aneurysm	1	1	1				
Coeliac artery compression syndrome	1	1	1				
Coeliac artery stenosis	5	2	5				
Coeliac disease	56	21	56			1	1
Colitis	388	76	209	63	179	2	5
Colitis ischaemic	102	25	102			2	2
Colitis microscopic	57	29	57			1	1
Colitis ulcerative	561	229	561			15	42
Constipation	1585	121	457	339	1128	10	15
Constipation neonatal	1			1	1		
Crohn's disease	289	116	289			48	88
Cyclic vomiting syndrome	5		2	2	3		
Defaecation disorder	37	2	11	16	26	1	1
Defaecation urgency	121	8	39	14	82		1
Dental alveolar anomaly	1		1				
Dental caries	13	1	3		10		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dental cyst	4		1	1	3		
Dental discomfort	60	3	9	11	51		
Dental dysaesthesia	3		1	1	2		
Dental necrosis	3	1	3				
Dental paraesthesia	37	3	12	2	25		
Dental plaque	2	1	1		1		
Dental pulp disorder	2		1		1		
Diabetic gastroenteropathy	1				1		
Diabetic gastroparesis	3		1	2	2		
Diabetic gastropathy	1	1	1				
Diaphragmatic hernia	4		4				
Diarrhoea	44169	1586	8238	8470	35931	58	167
Diarrhoea haemorrhagic	253	63	253			1	1
Diarrhoea neonatal	8	1	8				
Dieulafoy's vascular malformation	1				1		
Discoloured vomit	35	4	19	3	16	1	1
Diverticular fistula	1		1				
Diverticular perforation	3		3				
Diverticulum	39	5	24	6	15	1	1
Diverticulum intestinal	51	8	27	6	24		
Diverticulum intestinal haemorrhagic	11		11				
Dolichocolon acquired	1		1				
Dry mouth	2835	113	645	481	2190	6	15
Dumping syndrome	2			1	2		
Duodenal perforation						1	1
Duodenal stenosis	1		1				
Duodenal ulcer	18	6	18				1

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System Organ Class

Gastrointestinal disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Duodenal ulcer haemorrhage	13	5	13				
Duodenal ulcer perforation	3		3				
Duodenitis	18	3	10	5	8		
Duodenogastric reflux	22	3	8	4	14	1	1
Dysbiosis	14	2	5	5	9		
Dyschezia	75	13	35	13	40	1	1
Dyskinesia oesophageal	2	1	1	1	1		
Dyspepsia	2650	182	689	631	1961	3	7
Dysphagia	4190	403	1676	736	2514	8	23
Enamel anomaly	1			1	1		
Enlarged uvula	115	8	53	9	62		
Enteritis	105	11	51	14	54		1
Enterocolitis	51	7	51				
Enterocolitis haemorrhagic	26	13	26				
Enterocutaneous fistula	2		2				
Enterovesical fistula	3		3				
Eosinophilic colitis	3	2	3				
Eosinophilic gastritis	1	1	1				
Eosinophilic oesophagitis	14	4	7	3	7		
Epigastric discomfort	179	10	52	56	127		
Epiploic appendagitis	8	1	4	1	4		
Erosive oesophagitis	3	1	3				
Eructation	436	27	103	98	333	1	4
Faecalith	3	2	2	1	1		
Faecaloma	42	14	42				2
Faecal vomiting	11	1	11				
Faeces discoloured	360	24	108	70	252	1	3

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System Organ Class

Gastrointestinal disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Faeces hard	23	2	6	3	17		
Faeces pale	54	6	21	10	33		
Faeces soft	304	11	53	47	251		
Flatulence	1052	46	245	198	807		8
Food poisoning	57	3	25	2	32		
Frequent bowel movements	270	18	62	51	208	1	5
Functional gastrointestinal disorder	123	8	43	29	80	1	1
Gastric antral vascular ectasia	14		14				
Gastric dilatation	43	2	13	8	30		
Gastric disorder	303	18	79	58	224	1	2
Gastric fibrosis	1	1	1				
Gastric haemorrhage	44	12	44			1	1
Gastric hypermotility	1				1		
Gastric hypomotility	2			1	2		
Gastric mucosa erythema	4	1	2	2	2		
Gastric mucosal lesion	2		1		1		
Gastric perforation	5	3	5				
Gastric polyps	7		2		5		
Gastric stenosis	1		1				
Gastric ulcer	70	23	70				
Gastric ulcer haemorrhage	16	5	16				
Gastric ulcer perforation	2	2	2				
Gastric varices haemorrhage	2		2				
Gastric volvulus	2		2				
Gastritis	581	83	202	179	379	2	3
Gastritis erosive	19	3	19				
Gastritis haemorrhagic	4		4				

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System Organ Class

Gastrointestinal disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gastritis hypertrophic	1	1	1				
Gastroenteritis eosinophilic	3		1		2		
Gastrointestinal angiodysplasia	3	2	3				
Gastrointestinal disorder	1661	99	334	332	1327	1	4
Gastrointestinal fistula							1
Gastrointestinal haemorrhage	203	45	203				
Gastrointestinal hypermotility	30		8	12	22		
Gastrointestinal hypomotility	20	3	9	5	11		
Gastrointestinal inflammation	138	26	62	38	76		
Gastrointestinal motility disorder	93	5	15	22	78		
Gastrointestinal mucosa hyperaemia	1				1	1	1
Gastrointestinal mucosal disorder	6		5		1		
Gastrointestinal necrosis	38	12	38				
Gastrointestinal obstruction	7		7				
Gastrointestinal oedema	21	2	21				
Gastrointestinal pain	1238	72	294	353	944	1	3
Gastrointestinal perforation	8	2	8				
Gastrointestinal polyp haemorrhage	1		1				
Gastrointestinal scarring						2	3
Gastrointestinal sounds abnormal	145	6	32	40	113	1	1
Gastrointestinal toxicity	2	1	1		1		
Gastrointestinal tract irritation	34	3	6	14	28	1	1
Gastrointestinal ulcer	6		2		4		
Gastrointestinal wall thickening	15	1	9	1	6		
Gastrointestinal wall thinning	1		1				
Gastrooesophageal reflux disease	904	91	310	200	594	2	4
Gastrooesophageal sphincter insufficiency	2		1	1	1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gingival atrophy	2			2	2		
Gingival bleeding	538	44	163	135	375		1
Gingival blister	45	1	10	4	35		
Gingival cyst	2			1	2		
Gingival discolouration	15		4	6	11		
Gingival discomfort	60		8	11	52		1
Gingival disorder	45	3	9	14	36		
Gingival erosion	4	2	2	2	2		
Gingival erythema	30	5	10	4	20	1	1
Gingival hypertrophy	3		2		1		
Gingival oedema	43	1	3	17	40		
Gingival pain	470	25	125	93	345		
Gingival pruritus	6	1	2	2	4		
Gingival recession	22	5	8	7	14	2	2
Gingival swelling	300	21	77	51	223		
Gingival ulceration	22	4	7	4	15		
Gingivitis ulcerative	14	1	8	1	6		
Glossitis	206	15	61	32	145		
Glossodynia	790	39	198	112	592	1	1
Glossoptosis	7		5		2		
Haematemesis	317	81	317			1	4
Haematochezia	741	214	741			15	28
Haemoperitoneum	15	4	15				
Haemorrhagic ascites	1		1				
Haemorrhagic necrotic pancreatitis	1		1				
Haemorrhoidal haemorrhage	46	1	11	13	35		
Haemorrhoids	289	21	79	85	210	3	4

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System Organ Class

Gastrointestinal disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemorrhoids thrombosed	139	30	59	32	80		1
Hiatus hernia	81	9	39	10	42		
Hiatus hernia strangulated	1	1	1				
Hyperaesthesia teeth	138	4	25	32	113		
Hyperchlorhydria	51		14	14	37		
Hypertrophy of tongue papillae	18		2	4	16		
Hypoaesthesia oral	3878	183	1066	601	2812	1	6
Hypoaesthesia teeth	18	1	4	2	14		
Ileal perforation	1		1				
Ileus	47	6	47				
Ileus paralytic	34	6	34				
Immune-mediated pancreatitis	1	1	1				
Impaired gastric emptying	57	15	57				1
Incarcerated umbilical hernia	1		1				
Infantile colic	2	2	2				
Infantile spitting up	1			1	1		
Infantile vomiting	79	5	33	29	46		
Inflammatory bowel disease	70	31	69	1	1	3	3
Infrequent bowel movements	15	1	5	3	10	1	1
Inguinal hernia	27	6	14	7	13	1	1
Internal hernia	3		1	2	2		
Intestinal angina	1		1				
Intestinal angioedema	4		4				
Intestinal atony	3				3		
Intestinal barrier dysfunction	5			5	5		
Intestinal congestion	2	1	1		1		
Intestinal cyst	1	1	1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Intestinal dilatation	9	2	6	1	3		
Intestinal fibrosis	1				1		
Intestinal fistula	1		1				
Intestinal haemorrhage	84	28	84			1	2
Intestinal infarction	37	15	37				
Intestinal ischaemia	128	31	128				1
Intestinal mass	4	2	3	1	1		
Intestinal mucosal tear	1		1				
Intestinal obstruction	124	48	124			3	3
Intestinal perforation	30	13	30				
Intestinal polyp	2	1	2				
Intestinal prolapse	1	1	1				
Intestinal pseudo-obstruction	4	1	4				
Intestinal stenosis	3	1	3			1	1
Intestinal ulcer	8	1	8				
Intestinal vascular disorder	1	1	1				
Intra-abdominal fluid collection	13	6	12	1	1		
Intra-abdominal haematoma	12	1	12				
Intra-abdominal haemorrhage	27	7	27				1
Intussusception	32	4	32				
Irritable bowel syndrome	310	44	148	42	162	3	3
Ischaemic enteritis	1	1	1				
Jejunal perforation	1		1				
Large intestinal haemorrhage	10	1	10			1	1
Large intestinal obstruction	6	2	6				
Large intestinal stenosis	1		1				1
Large intestinal ulcer	7	3	7				

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Gastrointestinal disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Large intestinal ulcer haemorrhage	2		2				
Large intestine erosion	1	1	1				
Large intestine perforation	19	5	19			3	3
Large intestine polyp	13	2	8	2	5	1	1
Leukoplakia oral	8	4	8				
Levator syndrome	1				1		
Lip blister	205	11	49	27	156		
Lip discolouration	61	6	22	13	39		1
Lip disorder	118	4	28	11	90	1	1
Lip dry	235	16	57	45	178		
Lip erosion	10	1	6	1	4		
Lip erythema	90	3	20	8	70		
Lip exfoliation	34	2	9	7	25		
Lip haematoma	2		1		1		
Lip haemorrhage	35	7	16	4	19		
Lip oedema	809	39	283	98	526	4	10
Lip pain	310	22	91	41	219		
Lip pruritus	273	8	85	34	188		1
Lip scab	2	1	2				
Lip swelling	4179	252	1330	697	2849	2	7
Lip ulceration	56	5	16	11	40		
Loose tooth	26	7	12	6	14		
Lower gastrointestinal haemorrhage	9	1	9				
Lumbar hernia	2			2	2		
Malabsorption	22	4	10	6	12	1	1
Malignant dysphagia	1	1	1				
Mallory-Weiss syndrome	7	2	7				

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System Organ Class

Gastrointestinal disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Malocclusion	9	2	5	1	4	1	1
Malpositioned teeth	6	2	4	1	2		
Mechanical ileus	3		3				
Meconium peritonitis	2		2				
Megacolon	3	2	3				
Melaena	153	40	153				
Mesenteric arterial occlusion	6	1	6				
Mesenteric artery aneurysm	2	1	2				
Mesenteric artery embolism	5	1	5				
Mesenteric artery stenosis	3		3				1
Mesenteric artery thrombosis	19	3	19				1
Mesenteric haematoma	2	1	2				
Mesenteric haemorrhage	2		2				
Mesenteric panniculitis	16	1	13	3	3		
Mesenteric vascular insufficiency	1		1				
Mesenteric vascular occlusion	6	2	6				
Mesenteric vein thrombosis	130	39	130				
Mesenteric venous occlusion	1		1				
Mesenteritis	3		1	1	2		
Mouth cyst	16		4	2	12		
Mouth haemorrhage	242	31	119	41	123		1
Mouth swelling	694	49	244	96	450		
Mouth ulceration	932	71	312	135	620		3
Mucous stools	109	13	36	29	73		
Nausea	123930	4205	21728	26201	102202	132	421
Necrotising colitis	4	1	4				
Necrotising enterocolitis neonatal	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neonatal intestinal obstruction	1		1				
Neurogenic bowel	2		1		1		
Noninfective gingivitis	195	18	41	59	154		
Noninfective sialoadenitis	57	4	10	23	47		
Obstruction gastric	2		2				
Obstructive pancreatitis	9		9				
Obturator hernia	2	1	2				
Odynophagia	1471	37	264	167	1207		2
Oedema mouth	108	8	48	15	60		1
Oedematous pancreatitis	11	3	11				
Oesophageal achalasia	13	6	8		5		
Oesophageal dilatation	1		1				
Oesophageal discomfort	20	1	5	8	15	1	1
Oesophageal disorder	19	4	11	3	8		
Oesophageal food impaction	2	1	2				
Oesophageal haemorrhage	5	3	5				
Oesophageal irritation	6		2	2	4		
Oesophageal mass	2	1	2				
Oesophageal motility disorder	1			1	1		
Oesophageal mucosal blister	1			1	1		
Oesophageal obstruction	2	1	2				
Oesophageal oedema	8		5	3	3		
Oesophageal pain	100	6	28	29	72		
Oesophageal perforation	4		4				
Oesophageal rupture	3	2	3				
Oesophageal spasm	39	1	8	6	31		
Oesophageal stenosis	9	3	9				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oesophageal ulcer	7	2	7				
Oesophageal ulcer haemorrhage	2	1	2				
Oesophageal varices haemorrhage	8	2	8				
Oesophagitis	84	11	30	20	54		
Oesophagitis ulcerative	3	1	3				
Omental haemorrhage	1		1				
Omental infarction	15	4	12	2	3		
Oral blood blister	52	7	18	5	34		
Oral cavity fistula	1				1		
Oral discharge	2		1		1		
Oral discomfort	973	43	204	150	769		2
Oral disorder	240	15	62	44	178	1	1
Oral dysaesthesia	75	2	18	18	57		
Oral hyperaesthesia	2		1		1		
Oral lichenoid reaction	4		1		3		
Oral lichen planus	57	18	30	14	27		
Oral mucosa erosion	26	3	11	5	15		1
Oral mucosa haematoma	7		3	1	4		
Oral mucosal blistering	345	18	76	69	269		
Oral mucosal discolouration	8	1	3	1	5		
Oral mucosal eruption	104	6	26	15	78		
Oral mucosal erythema	103	9	29	18	74		
Oral mucosal exfoliation	34	3	11	3	23		
Oral mucosal hypertrophy	2			1	2		
Oral mucosal roughening	17		5	3	12		
Oral mucosal scab	3	1	1	1	2		
Oral pain	793	45	205	132	588		

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		I	C	I	C	I	C
Oral papule	8		1	2	7		
Oral pigmentation	2			1	2		
Oral pruritus	424	13	144	66	280		
Oral purpura	4		3		1		
Overflow diarrhoea	2	1	1		1		
Palatal disorder	34		6	8	28		
Palatal oedema	170	12	90	7	80	1	3
Palatal swelling	119	7	43	25	76	1	1
Palatal ulcer	6		2	2	4		
Pancreatic atrophy	1	1	1				
Pancreatic calcification	2		2				
Pancreatic cyst	17	6	9	2	8		
Pancreatic disorder	33	8	15	9	18		
Pancreatic duct dilatation	2		2				
Pancreatic enlargement	5	3	3	2	2		
Pancreatic failure	14	9	14				
Pancreatic haemorrhage	1		1				
Pancreatic infarction	1		1				
Pancreatic mass	2	1	2				
Pancreatic pseudocyst	3	1	2		1		
Pancreatic steatosis	8		4	1	4		
Pancreatitis	280	105	280			4	4
Pancreatitis acute	350	83	350			3	3
Pancreatitis chronic	13	4	13				
Pancreatitis haemorrhagic	1		1				
Pancreatitis necrotising	19	8	19				1
Pancreatitis relapsing	4		4				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Papilla of Vater sclerosis	1		1				
Paraesthesia oral	5963	212	1489	724	4474	5	20
Paresis anal sphincter	1			1	1		
Parotid duct obstruction	3		1	2	2		
Parotid gland enlargement	112	11	30	20	82		
Parotid lipomatosis	1				1		
Pelvic floor dysfunction	5	2	4	1	1		
Peptic ulcer	13	7	13				
Peptic ulcer haemorrhage	19	5	19				
Periodontal disease	5			3	5		
Periodontal inflammation	4			3	4		
Peristalsis visible	2		1		1		
Peritoneal adhesions	1	1	1				
Peritoneal disorder	3	1	2		1		
Peritoneal haematoma	2	1	2				
Peritoneal perforation	1		1				
Pharyngo-oesophageal diverticulum	1	1	1				
Pigmentation lip	2	1	1		1		
Plicated tongue	19	1	6	1	13		
Pneumatosis intestinalis	2	1	2				
Pneumoperitoneum	4	3	4				
Poor dental condition	2			1	2		
Portal hypertensive gastropathy	3	2	3				
Portal venous gas	2	1	2				
Post-tussive vomiting	4	2	2	1	2		
Pouchitis	1		1			1	1
Proctalgia	89	4	22	25	67		

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Gastrointestinal disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Proctitis	42	3	11	12	31		
Proctitis haemorrhagic	3	2	3				
Proctitis ulcerative	11	6	11				
Protein-losing gastroenteropathy	1	1	1				
Protrusion tongue	1		1				
Pylorospasm	1				1		
Ranula	2	1	2				
Rectal discharge	16		7	4	9		
Rectal fissure	1			1	1		
Rectal haemorrhage	421	103	421			3	10
Rectal lesion	1				1		
Rectal perforation	1		1				
Rectal polyp	2		1		1		
Rectal prolapse	8	1	4	1	4		1
Rectal spasm	2			1	2		
Rectal tenesmus	28	1	8	5	20		1
Rectal ulcer	4	1	4				
Rectourethral fistula	1		1				
Reflux gastritis	65	7	19	19	46		
Regurgitation	54	4	9	20	45		1
Retching	1048	41	273	177	775	1	6
Retroperitoneal effusion	1	1	1				
Retroperitoneal fibrosis	2		2				
Retroperitoneal haematoma	11	3	11				
Retroperitoneal haemorrhage	7	2	7				
Retroperitoneal mass	1			1	1		
Saliva altered	35		11	5	24		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Saliva discolouration	6		2		4		
Salivary duct obstruction	5		2	1	3		
Salivary gland calculus	4			1	4		
Salivary gland cyst	2	1	1	1	1		
Salivary gland disorder	18	2	10	3	8		
Salivary gland enlargement	88	8	28	18	60	2	3
Salivary gland mass	6	1	2	2	4		
Salivary gland mucocoele	3	1	2		1		
Salivary gland pain	85	2	17	13	68		1
Salivary hypersecretion	408	22	105	64	303		
Scalloped tongue	9		3	1	6		
Short-bowel syndrome	2	1	2			1	1
Small intestinal haemorrhage	18	3	18			1	1
Small intestinal obstruction	18	6	18				
Small intestinal perforation	4	1	4				
Small intestinal stenosis							1
Splenic artery aneurysm	2	1	2				
Stasis syndrome	2	1	2				
Steatorrhoea	12		5	3	7		
Stiff tongue	32	1	17	5	15		
Stomach mass	10	1	3	4	7		
Stomatitis	758	35	149	131	609	1	3
Strawberry tongue	6	1	4		2		
Subileus	16	2	12	3	4		
Submaxillary gland enlargement	25	3	5	6	20		
Superior mesenteric artery dissection	2	2	2				
Superior mesenteric artery syndrome	1		1				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Swollen tongue	3293	191	1238	458	2055	1	6
Teeth brittle	5		1	1	4		
Teething	45	2	9	8	36		
Terminal ileitis	12	3	12				
Thrombosis mesenteric vessel	12	2	12				
Tongue atrophy	2	2	2				
Tongue blistering	136	2	26	23	110		
Tongue coated	130	3	28	33	102		1
Tongue cyst	5		4		1		
Tongue discolouration	183	6	37	29	146		
Tongue discomfort	653	20	121	150	532	1	2
Tongue disorder	358	18	130	35	228		
Tongue dry	114	4	37	13	77		
Tongue dysplasia	1	1	1				
Tongue eruption	69	1	14	16	55		
Tongue erythema	118	6	29	17	89		1
Tongue exfoliation	11	1	2	4	9		
Tongue geographic	39	2	9	12	30		
Tongue haematoma	13	1	5	1	8		
Tongue haemorrhage	23	4	6	4	17	1	1
Tongue induration	1			1	1		
Tongue movement disturbance	68	8	37	11	31		
Tongue oedema	483	34	248	53	235	4	10
Tongue pigmentation	1				1		
Tongue polyp	2	1	1	1	1		
Tongue pruritus	260	9	83	32	177		1
Tongue rough	35		5	7	30		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tongue spasm	37	5	15	5	22	1	1
Tongue thrust	4			3	4		
Tongue ulceration	155	8	51	21	104		
Toothache	1410	57	279	353	1131	2	4
Tooth demineralisation	1				1		
Tooth deposit	3	1	2	1	1		
Tooth development disorder	1		1				
Tooth discolouration	15	1	6	1	9		
Tooth disorder	112	7	22	19	90		4
Tooth erosion	5	2	2	1	3		
Tooth impacted	5		1	1	4		
Tooth loss	41	1	15	18	26		
Tooth malformation	1				1		
Tooth pulp haemorrhage	1				1		
Tooth resorption	2			1	2		1
Tooth socket haemorrhage	3		1		2		
Transient lingual papillitis	2				2		
Trichoglossia	38	1	10	10	28		
Truncus coeliacus thrombosis	6	2	6				
Ulcerative duodenitis	1		1				
Ulcerative gastritis	1			1	1		
Umbilical hernia	8	3	4	2	4		1
Upper gastrointestinal haemorrhage	55	15	55				
Uvula deviation	1			1	1		
Uvulitis	21	2	10	4	11		
Varices oesophageal	9	2	6	1	3		
Varicose veins of abdominal wall	1		1				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vasculitis gastrointestinal	2	1	2				
Visceral venous thrombosis	12	1	12				
Volvulus	19	6	19				
Volvulus of small bowel	1		1				
Vomiting	38784	2384	10314	8948	28470	69	180
Vomiting projectile	189	20	98	18	91		
Walled-off pancreatic necrosis	1			1	1		
Total:	317811	16441	74713	64438	243098	533	1403

System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal organ growth	1	1	1				
Abscess sterile	1				1		
Absence of immediate treatment response	1		1				
Acute phase reaction	5	2	3		2		
Adhesion	21	1	6	4	15		
Administration site bruise	26	1	3	3	23		
Administration site discolouration	2		1		1		
Administration site discomfort	3		1	1	2		
Administration site erythema	28			7	28		
Administration site extravasation	3		1		2		
Administration site fibrosis	1				1		
Administration site haematoma	3			1	3		
Administration site hypersensitivity	2				2		
Administration site hypoaesthesia	2				2		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Administration site induration	2				2		
Administration site inflammation	2				2		
Administration site irritation	2				2		
Administration site joint discomfort	1				1		
Administration site joint erythema	2			1	2		
Administration site joint movement impairment	8		2	3	6		
Administration site joint pain	4				4		
Administration site lymphadenopathy	8			1	8		
Administration site movement impairment	15		1	4	14		
Administration site nerve damage	1		1				
Administration site oedema	29			6	29		
Administration site pain	663	1	2	27	661		
Administration site paraesthesia	6				6		
Administration site plaque	1			1	1		
Administration site pruritus	8			3	8		
Administration site rash	5				5		
Administration site reaction	27	1	2	3	25		
Administration site swelling	13			1	13		
Administration site urticaria	1				1		
Administration site warmth	3				3		
Administration site wound	2			1	2		
Adverse drug reaction	120	8	23	27	97	3	3
Adverse event	121	5	16	46	105		
Adverse food reaction	13	1	5	2	8		
Adverse reaction	165	11	23	94	142	1	1
Alcohol interaction	14	1	7	1	7		
Antidepressant discontinuation syndrome	2			1	2		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Apparent death	1		1				
Application site acne	5		2		3		
Application site alopecia	1			1	1		
Application site bruise	7			1	7		
Application site burn	2		1		1		
Application site coldness	3		1		2		
Application site dermatitis	1				1		
Application site discolouration	1				1		
Application site discomfort	3	1	1		2		
Application site dysaesthesia	4	1	1		3		
Application site erythema	198		3	11	195		
Application site haematoma	6	1	2		4		
Application site haemorrhage	7		2	2	5		
Application site hyperaesthesia	1				1		
Application site hypersensitivity	2				2		
Application site hypoaesthesia	25	4	4	10	21		
Application site induration	8			1	8		
Application site inflammation	5				5		
Application site joint erythema	1				1		
Application site joint inflammation	1				1		
Application site joint movement impairment	4			4	4		
Application site joint pain	3				3		
Application site joint swelling	6				6		
Application site lymphadenopathy	18			4	18		
Application site movement impairment	25	1	1	4	24		
Application site nerve damage	1		1				
Application site nodule	1			1	1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Application site odour	1				1		
Application site oedema	8			3	8		
Application site pain	1509	2	5	63	1504		
Application site paraesthesia	4		1	1	3		
Application site perspiration	1				1		
Application site plaque	1				1		
Application site pruritus	35			1	35		
Application site rash	6			1	6		
Application site reaction	140	1	1	5	139		
Application site scab	1		1				
Application site scar	1				1		
Application site swelling	287	1	1	13	286		
Application site thrombosis	1	1	1				
Application site vesicles	6		2		4		
Application site warmth	19			1	19		
Asthenia	59447	2729	11224	10891	48223	64	190
Atrophy	31	12	22	5	9		
Axillary pain	14735	923	3161	4146	11574	3	16
Brain death	50	12	50				
Breakthrough pain	6		2	1	4		
Breast implant palpable	1				1		
Calcinosis	14	3	6	3	8		
Capsular contracture associated with breast implant	8	1	4	1	4		
Capsular contracture associated with implant	2		1		1		
Cardiac death	76	21	76				
Catheter site haematoma	1		1				
Catheter site haemorrhage	1				1		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Catheter site injury	1		1				1
Catheter site pain	5	1	1	1	4		
Catheter site swelling							1
Catheter site thrombosis	2		2				
Challenge site reaction	2				2		
Chest discomfort	20378	2718	7293	5716	13085	17	39
Chest pain	40680	5638	15477	12243	25203	53	136
Chills	128172	2806	14441	30528	113731	89	245
Chronic disease	8	1	3	3	5		
Chronic fatigue syndrome	413	119	254	99	159	1	3
Chronic inflammatory response syndrome	5	4	5				
Clinical death	1	1	1				
Complication associated with device	16	1	6	4	10		
Complication of device removal	2				2		
Concomitant disease aggravated	1026	42	90	679	936		
Concomitant disease progression	33	6	20	10	13		
Condition aggravated	8805	1503	4316	1648	4489	16	35
Crepitations	73	9	24	9	49		
Critical illness	5	1	5				
Crying	904	36	241	152	663	1	3
Cyst	287	41	80	98	207	3	3
Cyst rupture	16	1	5	5	11		
Death	2995	646	2995			5	6
Death neonatal	7	1	7				
Decapitation	1		1				
Decreased activity	162	25	65	47	97		
Decreased gait velocity	6		2		4		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Deformity	26	3	10	3	16		
Dehiscence	1			1	1		
Developmental delay	5	2	2	2	3		
Developmental regression	2	1	1	1	1		
Device embolisation	1		1				
Device related thrombosis	2	1	2				
Diet failure	1				1		
Discharge	92	5	23	27	69		
Discomfort	5945	391	1526	1136	4419	3	14
Disease complication	5		2	2	3		
Disease prodromal stage	2	1	1		1		1
Disease progression	133	24	93	12	40	1	2
Disease propensity	2			2	2		
Disease recurrence	3559	542	2665	207	894	2	22
Disease susceptibility	26	1	1	20	25		
Drowning	30	4	30				
Drug-device interaction	4	1	1	2	3		
Drug-disease interaction	2		1	1	1		
Drug effective for unapproved indication	5				5		
Drug effect less than expected	6			2	6		
Drug-genetic interaction	1			1	1		
Drug ineffective	40393	25773	40350	20	43	888	1157
Drug ineffective for unapproved indication	1				1		
Drug interaction	422	35	150	85	272	3	10
Drug intolerance	56	5	16	20	40		
Drug resistance	7	1	4	1	3		
Drug tolerance	1				1		

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System Organ Class

General disorders and administration site conditions

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Drug tolerance decreased	3		2		1		
Drug withdrawal syndrome	8		2	1	6		
Drug withdrawal syndrome neonatal	1				1		
Dysplasia	7	1	3	1	4		
Early satiety	4			1	4		
Effusion	57	10	27	9	30		
Embolia cutis medicamentosa	2		2				
Enanthema	22	1	9	3	13		
Encapsulation reaction	3			2	3		
Energy increased	178	4	17	33	161		1
Exercise tolerance decreased	1533	236	455	734	1078	1	3
Exercise tolerance increased	4			2	4		
Extensive swelling of vaccinated limb	3610	203	519	1414	3091		
Extravasation	11		4	1	7		
Eye complication associated with device	2		1	1	1		
Face oedema	1649	124	618	280	1031	4	8
Facial discomfort	308	5	54	73	254		
Facial pain	1638	126	520	320	1118	1	2
Fatigue	234052	8366	33844	58770	200208	308	889
Fat necrosis	14	3	9	1	5		
Fat tissue decreased	3			2	3		
Fat tissue increased	17	4	9	2	8		
Feeling abnormal	16662	870	4411	2211	12251	13	36
Feeling cold	11489	416	2108	1657	9381	12	34
Feeling drunk	567	21	147	92	420		
Feeling hot	17980	519	2775	5340	15205	8	21
Feeling jittery	348	17	85	58	263		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Feeling of body temperature change	2048	202	783	346	1265	1	6
Feeling of relaxation	20		3	4	17		
Fever neonatal	8	2	8				
Fibrosis	28	4	18	5	10		
First bite syndrome	1	1	1				
Foaming at mouth	61	11	38	5	23		
Food interaction	4				4		
Foreign body reaction	6	1	2		4		
Gait deviation	14	4	10	2	4		
Gait disturbance	7579	937	3137	1453	4442	14	37
Gait inability	1776	270	983	194	793		5
Generalised oedema	275	54	141	59	134		
General physical health deterioration	2718	341	1329	621	1389	2	6
General symptom	39	1	11	4	28	2	2
Glassy eyes	43	1	11	7	32		
Granuloma	29	5	8	11	21		
Gravitational oedema	23	4	12	2	11	1	2
Haemorrhagic cyst	8	2	8				1
Hanging	1				1		
Hangover	280	14	87	40	193	1	2
Herbal interaction	1				1		
Hernia	46	9	19	8	27	1	1
Hernia pain	11			2	11		
High-pitched crying	4			1	4		
Humidity intolerance	1				1		
Hunger	333	9	48	68	285	1	2
Hyperplasia	11	2	5	2	6		

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General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hyperpyrexia	1094	248	1094			11	31
Hyperthermia	1101	53	321	150	780		
Hyperthermia malignant	4	2	4				
Hypertrophy	19	4	7	6	12		
Hypothermia	450	104	450			1	4
Idiopathic environmental intolerance	6		1	4	5		
Idiosyncratic drug reaction	3				3		
Ill-defined disorder	78	14	26	22	52	1	3
Illness	6975	585	2494	968	4481	19	45
Immediate post-injection reaction	8	1	3	2	5		
Impaired healing	136	15	37	53	99	2	4
Impaired self-care	24	6	16	1	8		
Implant site dermatitis	1				1		
Implant site discolouration	2				2		
Implant site erythema	4			1	4		
Implant site extravasation	4		2		2		
Implant site haemorrhage	1	1	1				
Implant site hypersensitivity	3				3		
Implant site induration	3		1		2		
Implant site inflammation	4		1	1	3		
Implant site irritation	1				1		
Implant site nodule	2				2		
Implant site oedema	4				4		
Implant site pain	16	1	3	4	13		
Implant site paraesthesia	1				1		
Implant site pruritus	2				2		
Implant site rash	1				1		

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General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Implant site reaction	5			3	5		
Implant site swelling	15		1	1	14		
Implant site urticaria	1				1		
Implant site warmth	4		1	1	3		
Inadequate analgesia	11	1	5	2	6		
Incarcerated hernia	2	1	2				
Induration	2128	14	100	83	2028		
Inflammation	5886	529	1672	1031	4214	10	14
Inflammatory pain	133	12	50	38	83		
Influenza like illness	28373	979	4615	5951	23758	13	45
Infusion site bruising	1				1		1
Infusion site erythema	3				3		
Infusion site extravasation	2			1	2		1
Infusion site haematoma	1				1		
Infusion site haemorrhage	2	1	2				1
Infusion site hypoaesthesia	1				1		
Infusion site induration	1				1		
Infusion site joint inflammation	2				2		
Infusion site joint pain	2				2		
Infusion site joint swelling	4				4		
Infusion site lymphadenopathy	1				1		
Infusion site mass							1
Infusion site mobility decreased	16	1	1	9	15		
Infusion site pain	8			1	8	1	2
Infusion site paraesthesia	1				1		
Infusion site pruritus	3				3		
Infusion site reaction	1			1	1		

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General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Infusion site streaking	1				1		
Infusion site swelling	2				2		1
Infusion site urticaria	1				1		
Infusion site warmth	5		1	2	4		
Inhibitory drug interaction	29	2	9	3	20		
Injected limb mobility decreased	1974	70	225	492	1749		1
Injection site alopecia	1				1		
Injection site atrophy	3		2	1	1		
Injection site bruising	55	2	3	11	52	2	2
Injection site coldness	2				2		
Injection site cyst	3				3		
Injection site deformation	7		1	2	6		
Injection site discolouration	16			4	16		
Injection site discomfort	71		2	12	69		
Injection site erythema	1148	13	32	155	1116		
Injection site extravasation	37			8	37		
Injection site granuloma	2				2		
Injection site haematoma	50		4	6	46		
Injection site haemorrhage	45	1	2	6	43		
Injection site hyperaesthesia	2				2		
Injection site hypersensitivity	36		4	6	32		
Injection site hypertrophy	1				1		
Injection site hypoaesthesia	189	5	11	59	178		
Injection site indentation	19	1	6	1	13		
Injection site induration	186		1	9	185		
Injection site inflammation	105	1	2	14	103		
Injection site injury	1				1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Injection site irritation	4			1	4		
Injection site joint discomfort	1				1		
Injection site joint erythema	2				2		
Injection site joint inflammation	1				1		
Injection site joint movement impairment	19	1	2	2	17		
Injection site joint pain	33		1	1	32		
Injection site joint swelling	4			1	4		
Injection site joint warmth	2				2		
Injection site lymphadenopathy	26	1	3	7	23		
Injection site macule	2				2		
Injection site mass	144	6	20	10	124		1
Injection site movement impairment	35	3	6	5	29		
Injection site muscle atrophy	4		2	1	2		
Injection site muscle weakness	86	7	12	36	74		
Injection site necrosis	2	1	2				
Injection site nerve damage	2		2				
Injection site nodule	10			1	10		
Injection site oedema	304			4	304		
Injection site pain	7520	23	104	660	7416	6	9
Injection site papule	1				1		
Injection site paraesthesia	86	1	3	11	83		
Injection site pruritus	492	4	13	79	479		
Injection site rash	127	2	7	19	120		
Injection site reaction	466	6	39	25	427		
Injection site scab	2				2		
Injection site scar	3				3		
Injection site swelling	757	7	16	204	741	2	2

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Injection site thrombosis	1	1	1				
Injection site ulcer	2	1	1	1	1		
Injection site urticaria	73	3	6	7	67		
Injection site vesicles	12			2	12		
Injection site warmth	192	2	9	13	183	1	1
Injury associated with device	24	1	4	1	20		1
Instillation site haemorrhage	1			1	1		
Instillation site hyperaesthesia	1				1		
Instillation site pain	2				2		
Instillation site warmth	3		1		2		
Irritability postvaccinal	64		5	12	59		
Lipogranuloma	1			1	1		
Lithiasis	15	2	8	2	7		
Localised oedema	717	63	198	167	519	2	4
Local reaction	2002	16	183	390	1819	1	1
Loss of control of legs	109	29	109			1	1
Loss of therapeutic response	3		2	1	1		
Malaise	141773	3157	14648	29130	127125	178	428
Masked fever	1			1	1		
Mass	926	60	207	152	719	2	4
Maxillofacial pain	2			2	2		
Medical device discomfort	3			2	3		
Medical device pain	5		1	1	4		
Medical device site cyst	1		1				
Medical device site granuloma	1				1		
Medical device site inflammation	1				1		
Medical device site joint inflammation	3			2	3	1	1

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Medical device site joint swelling	2				2		
Medical device site lymphadenopathy	1			1	1		
Medical device site movement impairment	2				2		
Medical device site oedema	1			1	1		
Medical device site pain	2			1	2		
Medical device site paraesthesia	1			1	1		
Medical device site pruritus	1	1	1				
Medical device site rash	2	1	1	1	1		
Medical device site recall reaction	1				1		
Metaplasia	3		1		2		
Meteoropathy	5	1	1	4	4		
Moaning	59	4	26	13	33	1	1
Mucosal atrophy	1			1	1		
Mucosal discolouration	5		1	1	4		
Mucosal disorder	81	4	22	23	59		
Mucosal dryness	103	14	24	31	79		1
Mucosal erosion	4	1	2	2	2		
Mucosal exfoliation	1			1	1		
Mucosal haemorrhage	40	4	20	9	20		
Mucosal hyperaemia	5	1	2		3		
Mucosal hypertrophy	7	1	2	1	5		
Mucosal inflammation	83	5	18	41	65	3	3
Mucosal membrane hyperplasia	1			1	1		
Mucosal necrosis	1	1	1				
Mucosal pain	11	1	1	4	10		
Mucosal roughness	1				1		
Mucosal ulceration	11	2	5	4	6		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mucosa vesicle	5		1	1	4		
Multimorbidity	4		3		1		
Multi-organ disorder	27	5	23	1	4		
Multiple organ dysfunction syndrome	311	82	311				1
Necrobiosis	1				1		
Necrosis	57	18	57				
Neonatal multi-organ failure	1		1				
No adverse event	43			20	43		
Nodule	2083	37	161	134	1922	1	2
Non-cardiac chest pain	197	9	46	81	151		
Non-pitting oedema	13	2	4	3	9		
Nonspecific reaction	8		3		5	1	1
No reaction on previous exposure to drug	22	1	3	4	19		
Nyctalgia	3	1	1	1	2		
Obstruction	28	7	14	3	14	2	3
Oedema	3747	169	682	529	3065	5	8
Oedema due to cardiac disease	6	3	5	1	1		
Oedema due to hepatic disease	1		1				
Oedema due to renal disease	1	1	1				
Oedema mucosal	87	10	34	24	53		
Oedema peripheral	4000	411	1359	863	2641	4	17
Oral administration complication	4		1	1	3		
Organ failure	53	25	45	5	8		
Pacemaker generated arrhythmia	2		1		1		
Pacemaker syndrome	1		1				
Pain	79973	3556	14474	12817	65499	58	178
Papillitis	9		2	3	7		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Paradoxical drug reaction	4	1	2	2	2		
Pelvic mass	2	1	2				
Perforated ulcer	1		1				
Perforation	7		5	1	2		
Performance status decreased	564	93	161	265	403	2	2
Peripheral swelling	15784	1196	4742	2974	11042	18	52
Phantom shocks	2		1		1		
Physical deconditioning	662	39	175	104	487		
Pneumatosis	4		3		1		
Polyp	43	7	25	8	18	1	1
Polyserositis	40	17	40				
Potentiating drug interaction	35	1	3	2	32		
Precancerous condition						1	2
Pre-existing condition improved	106	4	7	31	99	1	1
Pre-existing disease	37	1	1	36	36		
Premature ageing	3		1		2		
Premature baby death	4	2	4				
Product intolerance	5		1	3	4		
Prolapse	12		2	8	10	1	1
Prosthetic cardiac valve thrombosis	3		3				
Pseudoallergic reaction	7	1	3	2	4		
Pseudoangina	1		1				
Pseudocyst	4		1	2	3		
Pseudohemia	1				1		
Pseudopolyp	1		1				
Puncture site bruise	28	3	10	1	18		
Puncture site discharge	1		1				

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Puncture site erythema	11			2	11		
Puncture site haematoma	3		3				
Puncture site haemorrhage	4		1		3		
Puncture site induration	16				16		
Puncture site oedema	17		1	2	16		
Puncture site pain	128	1	3	28	125		
Puncture site pruritus	6				6		
Puncture site reaction	7			1	7		
Puncture site swelling	10		1	3	9		
Pyrexia	227782	6469	29415	50937	198367	173	546
Radiation interaction	1				1		
Rebound effect	2		1	1	1		
Renin-angiotensin system inhibition	1			1	1		
Retention cyst	2	1	1		1		
Scar inflammation	21	2	3	11	18		
Screaming	96	6	33	23	63		
Secretion discharge	307	16	83	82	224		1
Sensation of blood flow	64	2	17	13	47		
Sensation of foreign body	1527	63	481	413	1046		
Sense of oppression	323	23	80	108	243		2
Sensitivity to weather change	29	1	6	9	23		
Serositis	17	1	10	3	7		
Shoulder injury related to vaccine administration	302	91	165	68	137		
Sick building syndrome	1		1				
Sluggishness	515	20	75	109	440		
Soft tissue inflammation	18	1	4	7	14		
Stenosis	51	13	32	8	19		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Stent-graft endoleak	5	3	5				
Steroid dependence	2		1	1	1		
Strangulated hernia	1	1	1				
Sudden cardiac death	105	27	105				
Sudden death	698	139	698			1	2
Sudden infant death syndrome	7	6	7				
Sudden unexplained death in epilepsy	1		1				
Supraclavicular fossa pain	10			10	10		
Suprapubic pain	13	1	6	3	7		
Swelling	16998	1057	3614	2981	13384	10	23
Swelling face	6615	389	1943	1234	4672	4	13
Symptom masked	1				1		
Symptom recurrence	72	11	30	18	42		
Systemic inflammatory response syndrome	137	32	137				1
Systemic leakage	1		1				
Temperature intolerance	231	26	81	52	150	1	1
Temperature regulation disorder	654	16	69	100	585	1	1
Tenderness	2772	134	480	536	2292	5	14
Terminal agitation	1	1	1				
Terminal state	12	1	12			2	3
Therapeutic product effect decreased	42	5	8	15	34	8	12
Therapeutic product effect delayed	5	1	2	1	3		1
Therapeutic product effect incomplete	8	2	5	2	3		3
Therapeutic product effect increased	4		1	3	3		
Therapeutic product effect prolonged	2		1		1		
Therapeutic product effect variable	1				1		
Therapeutic product ineffective	6	1	3	1	3		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Therapeutic response changed	5			5	5		
Therapeutic response decreased	12	2	4	2	8	2	3
Therapeutic response delayed	1	1	1				
Therapeutic response increased	1				1		
Therapeutic response shortened	3	1	1	2	2	3	3
Therapeutic response unexpected	2000	9	46	644	1954	1	1
Therapy non-responder	5	1	3	2	2		1
Therapy partial responder	78			78	78		
Therapy responder	1			1	1		
Thirst	1984	89	444	359	1540		3
Thirst decreased	39	2	10	11	29		
Tissue discolouration	2			1	2		
Tissue infiltration	7		1		6		
Tissue irritation	3				3		
Tissue rupture	3	1	2		1		
Treatment failure	4	2	3	1	1		
Treatment noncompliance	2	1	2			1	1
Ulcer	159	13	57	38	102		
Ulcer haemorrhage	13	2	13				
Unevaluable event	232	9	13	141	219	1	2
Unmasking of previously unidentified disease	8	5	6	2	2		
Vaccination failure	37547	24194	37542	4	5	221	383
Vaccination site abscess sterile	6	1	4	2	2		
Vaccination site anaesthesia	16	1	4	4	12		
Vaccination site atrophy	23		6	6	17		
Vaccination site bruising	1642	47	262	282	1380	2	7
Vaccination site calcification	4		2	1	2		

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General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaccination site coldness	74		8	13	66		
Vaccination site cyst	19		3	8	16		
Vaccination site dermatitis	37	2	8	4	29		
Vaccination site discharge	45	1	6	8	39		1
Vaccination site discolouration	418	7	51	71	367	1	2
Vaccination site discomfort	2308	27	146	410	2162	1	4
Vaccination site dryness	24	1	2	8	22		
Vaccination site dysaesthesia	59	2	8	13	51		
Vaccination site eczema	57	2	4	14	53		
Vaccination site erosion	9			2	9		
Vaccination site erythema	27556	326	1689	6869	25867	5	16
Vaccination site eschar	1			1	1		
Vaccination site exfoliation	12		1	2	11		
Vaccination site extravasation	74	2	8	15	66		
Vaccination site fibrosis	3	1	2		1		
Vaccination site granuloma	21	2	4	6	17		
Vaccination site haematoma	4417	19	110	1233	4307		1
Vaccination site haemorrhage	674	31	133	120	541	1	4
Vaccination site hyperaesthesia	133	6	29	32	104		
Vaccination site hypersensitivity	303	3	22	69	281		
Vaccination site hypertrophy	9		2	1	7		
Vaccination site hypoaesthesia	761	42	164	199	597		1
Vaccination site induration	2933	47	226	532	2707		1
Vaccination site inflammation	16133	89	292	4466	15841	1	4
Vaccination site injury	138	6	12	17	126		1
Vaccination site irritation	153	4	25	29	128	1	1
Vaccination site ischaemia	3		3				

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaccination site joint discomfort	31	3	7	8	24		
Vaccination site joint effusion	4		1		3		
Vaccination site joint erythema	238	2	19	32	219		
Vaccination site joint inflammation	52	3	10	16	42		
Vaccination site joint movement impairment	640	26	107	89	533		1
Vaccination site joint pain	664	25	77	124	587		
Vaccination site joint swelling	227	3	11	42	216		
Vaccination site joint warmth	19	1	3	5	16		
Vaccination site laceration	1			1	1		
Vaccination site lymphadenopathy	5414	56	157	4027	5257		1
Vaccination site macule	41	1	1	8	40		
Vaccination site mass	2521	118	590	328	1931		1
Vaccination site movement impairment	2618	108	502	687	2116		
Vaccination site necrosis	26	11	26				
Vaccination site nerve damage	43	4	15	7	28		1
Vaccination site nodule	260	6	25	36	235		
Vaccination site oedema	3380	45	291	730	3089		2
Vaccination site pain	189777	2063	9383	46492	180394	136	319
Vaccination site pallor	9	1	2	1	7		
Vaccination site papule	82		5	16	77		
Vaccination site paraesthesia	1015	29	167	221	848		4
Vaccination site phlebitis	5		1		4		
Vaccination site photosensitivity reaction	7		1	1	6		
Vaccination site plaque	38	1	4	11	34		
Vaccination site pruritus	9979	145	735	2304	9244	2	7
Vaccination site rash	2422	77	381	434	2041	1	3
Vaccination site reaction	16160	610	2076	6306	14084	2	6

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaccination site recall reaction	7			2	7		
Vaccination site scab	53	1	7	11	46		
Vaccination site scar	57	2	6	11	51		
Vaccination site streaking	6		1	2	5		
Vaccination site swelling	39932	404	1868	10074	38064	42	85
Vaccination site thrombosis	15	2	15				
Vaccination site ulcer	20	2	6	5	14		
Vaccination site urticaria	711	20	120	88	591	1	2
Vaccination site vasculitis	3				3		
Vaccination site vesicles	267	10	49	48	218		1
Vaccination site warmth	15820	96	680	3924	15140	1	3
Vaccine positive rechallenge	6		2	1	4		
Vascular stent occlusion	3	2	3				
Vascular stent stenosis	6	3	6				
Vascular stent thrombosis	16	6	16				
Vessel puncture site bruise	3				3		
Vessel puncture site erythema	2			1	2		
Vessel puncture site haematoma	4			1	4		
Vessel puncture site haemorrhage	3		1	1	2		
Vessel puncture site inflammation	1			1	1		
Vessel puncture site injury	4				4		
Vessel puncture site pain	1			1	1		
Vessel puncture site reaction	1	1	1				
Vessel puncture site swelling	2			1	2		
Visceral oedema	3	1	3				
Visceral pain	13	1	3	5	10		
Withdrawal syndrome	56	1	26	3	30		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Xerosis	13	4	5	3	8		
Total:	1605985	106203	302991	348815	1302994	2507	5331

System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute hepatic failure	39	13	39				
Alcoholic liver disease	1		1				
Allergic hepatitis	3		3				
Alloimmune hepatitis	2	1	2				
Autoimmune cholangitis	1		1				
Autoimmune hepatitis	188	99	188				
Bile duct stenosis	3	1	3				
Bile duct stone	16	5	16				
Biliary cirrhosis	2	1	2				
Biliary colic	105	14	52	22	53	2	3
Biliary cyst	10		3	1	7		
Biliary dilatation	15	2	15				
Biliary fistula	1	1	1				
Biliary obstruction	1	1	1				
Biliary tract disorder	8		5		3		
Budd-Chiari syndrome	6	3	6				
Cardiac cirrhosis	5	2	5				
Cholangitis	40	13	40				
Cholangitis acute	9	3	9				
Cholangitis sclerosing	6	2	6			1	1

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cholecystitis	101	32	101			2	3
Cholecystitis acute	32	6	32				
Cholecystitis chronic	1		1				
Cholecystocholangitis	1	1	1				
Cholelithiasis	193	24	97	48	96	2	5
Cholestasis	122	37	122			1	2
Cholestasis of pregnancy	3	3	3			1	1
Cholestatic liver injury	11	2	11				
Chronic hepatic failure	2		2				
Chronic hepatitis	4	3	4				
Cirrhosis alcoholic	2	1	2				
Congestive hepatopathy	21	7	21				
Deficiency of bile secretion	3		3				
Drug-induced liver injury	56	23	56				
Fatty liver alcoholic	1		1				
Gallbladder cholesterolosis	1		1				
Gallbladder disorder	59	7	29	12	30	2	3
Gallbladder enlargement	15	3	15				
Gallbladder hypofunction	1		1				
Gallbladder obstruction	1	1	1				
Gallbladder oedema	9	1	9				
Gallbladder polyp	8	1	3	2	5		
Gallbladder rupture	1		1				
Granulomatous liver disease	3	1	3				
Hepatic artery embolism	1		1				
Hepatic artery stenosis	1	1	1				
Hepatic artery thrombosis	6	2	6				

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hepatic atrophy	2	1	2				
Hepatic calcification	1				1		
Hepatic cirrhosis	51	21	51			1	1
Hepatic cyst	53	4	17	14	36		1
Hepatic cytolysis	242	81	242				
Hepatic failure	104	32	104			2	3
Hepatic fibrosis	8	5	8				
Hepatic function abnormal	386	72	232	50	154		1
Hepatic haematoma	1		1				
Hepatic haemorrhage	9	1	9				
Hepatic hypertrophy	2				2		
Hepatic infarction	14	5	14				
Hepatic ischaemia	1		1				
Hepatic lesion	24	5	17	4	7		
Hepatic mass	18	3	7	6	11		
Hepatic necrosis	6		6				
Hepatic pain	253	24	70	74	183		
Hepatic perfusion disorder	2		2				
Hepatic steatosis	155	23	67	33	88	1	2
Hepatic vascular thrombosis	2	1	2			1	1
Hepatic vein dilatation	1		1				
Hepatic vein occlusion	1	1	1				
Hepatic vein thrombosis	11	4	11				
Hepatitis	258	104	258			1	1
Hepatitis acute	113	33	113				
Hepatitis alcoholic	2		2				
Hepatitis cholestatic	32	11	32				

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hepatitis chronic active	1		1				
Hepatitis fulminant	10	6	10				
Hepatitis neonatal	1	1	1				
Hepatitis toxic	16	5	16				
Hepatobiliary cyst	2			2	2		
Hepatobiliary disease	1				1		
Hepatocellular injury	29	9	29				
Hepatomegaly	128	17	63	27	65		1
Hepatorenal failure	3	1	3				
Hepatorenal syndrome	7	2	7			1	1
Hepatosplenomegaly	32	7	16	10	16		
Hepatotoxicity	7	5	7				
Hydrocholecystis	6	1	6				
Hyperbilirubinaemia	50	11	50				
Hyperbilirubinaemia neonatal	2		2				
Hypertransaminasaemia	71	11	46	7	25		2
Immune-mediated cholangitis	1		1				
Immune-mediated hepatic disorder	2	1	2			1	1
Immune-mediated hepatitis	3	1	3				
Ischaemic hepatitis	11	5	11				
Jaundice	341	65	210	54	131	1	2
Jaundice cholestatic	20	1	20				
Jaundice hepatocellular	1	1	1				
Liver disorder	320	42	179	55	141	1	2
Liver injury	106	34	106			3	3
Liver sarcoidosis	2	2	2				
Liver tenderness	7	1	3	1	4		

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mixed liver injury	16	4	16				
Neonatal hepatomegaly	1	1	1				
Nodular regenerative hyperplasia	1	1	1				
Non-alcoholic fatty liver	3	2	2		1		
Non-alcoholic steatohepatitis	2	2	2				
Non-cirrhotic portal hypertension	1	1	1				
Ocular icterus	64	12	28	14	36		
Peliosis hepatis	1	1	1				
Perihepatic discomfort	2			1	2		
Periportal oedema	3		3				
Pneumobilia	1		1				
Portal hypertension	9	3	9				
Portal vein dilatation	2	1	2				
Portal vein embolism	2		2				
Portal vein occlusion	4	2	4				
Portal vein phlebitis	3	1	3				
Portal vein thrombosis	171	50	171				3
Portosplenomesenteric venous thrombosis	17	7	17				
Primary biliary cholangitis	17	6	13	3	4		
Sphincter of Oddi dysfunction	2		2				
Steatohepatitis	1		1				
Subacute hepatic failure	2		2				
Subcapsular hepatic haematoma	1		1				
Venoocclusive liver disease	2	2	2				
Total:	4380	1073	3276	440	1104	24	43

System Organ Class

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Allergic oedema	52	6	30	3	22		
Allergic reaction to excipient	70	7	37	4	33		
Allergy to animal	43	8	17	16	26		
Allergy to arthropod bite	55	3	14	8	41		
Allergy to arthropod sting	63	4	18	17	45		
Allergy to chemicals	38	2	14	8	24	2	2
Allergy to fermented products	1	1	1				
Allergy to metals	11	2	3	3	8		
Allergy to plants	5		1		4		
Allergy to sting	6			2	6		
Allergy to synthetic fabric	1				1		
Allergy to vaccine	723	26	324	50	399	2	7
Amyloidosis	12	4	12				
Amyloidosis senile	3		1	1	2		
Anamnestic reaction	12	1	4	4	8		
Anaphylactic reaction	7326	793	7326			9	19
Anaphylactic shock	1212	233	1212			5	12
Anaphylactoid reaction	201	33	201				1
Anaphylactoid shock	8		8				
Anti-neutrophil cytoplasmic antibody positive vasculitis	42	13	42				
ASIA syndrome	4	4	4				
Atopy	28	1	4	7	24		
Atrophic thyroiditis	1		1				
Autoimmune disorder	570	241	569	1	1	6	6
Autoinflammatory disease	14	3	8	2	6		
Bacille Calmette-Guerin scar reactivation	131	8	20	31	111		
Caffeine allergy	2			2	2		

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cell-mediated immune deficiency	3		3				
Chronic graft versus host disease	12	10	12				
Contrast media allergy	7		4		3		
Contrast media reaction	2		2			1	1
Corneal graft rejection	32	13	32				
Cross sensitivity reaction	6		1	2	5		
Cytokine release syndrome	11	5	11				
Cytokine storm	34	9	34				
Decreased immune responsiveness	129	16	38	45	91	1	2
Device allergy	1			1	1		
Drug hypersensitivity	438	41	180	43	258	6	10
Dust allergy	11	3	4	4	7		
Eosinophilic granulomatosis with polyangiitis	31	18	31				
Food allergy	301	45	114	88	187	2	3
Graft versus host disease	8	2	8				
Graft versus host disease in eye	1		1				
Haemophagocytic lymphohistiocytosis	93	43	93			1	2
Hashitoxicosis	2	1	2				
Heart transplant rejection	3	1	3				
Human seminal plasma hypersensitivity	1				1		
Humoral immune defect	2	1	2				
Hypersensitivity	9587	703	3670	1653	5917	28	52
Hypocomplementaemia	3	1	1		2		
Hypogammaglobulinaemia	52	20	52				
Immune-mediated adverse reaction	44	8	28	6	16		
Immune reconstitution inflammatory syndrome	6	1	6				
Immune system disorder	699	104	256	218	443	1	3

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Immunisation reaction	7846	233	487	4363	7359	12	22
Immunodeficiency	140	64	140			10	16
Immunodeficiency common variable	4		4				
Immunosuppression	34	12	34			5	6
Infusion related hypersensitivity reaction	4		1		3		
Iodine allergy	1			1	1	2	2
Jarisch-Herxheimer reaction	2				2		
Kidney transplant rejection	8	5	8				
Liver transplant rejection	3	1	3				
Loefgren syndrome	14	7	14			1	1
Lung transplant rejection	3		3				
Milk allergy	15	4	6	7	9		
Mite allergy	39	8	10	18	29		
Multiple allergies	54	12	25	14	29		1
Multisystem inflammatory syndrome	50	43	50				
Multisystem inflammatory syndrome in adults	19	10	19				
Multisystem inflammatory syndrome in children	74	38	74				
Mycotic allergy	3			1	3		
Oral allergy syndrome	15	3	9	2	6	1	1
Overlap syndrome	4	2	2	1	2		
Perfume sensitivity	11	4	8		3		
Polymers allergy	18	6	8	8	10		
Primary amyloidosis	1		1				
Reaction to azo-dyes	1	1	1				
Reaction to colouring	3		2		1		
Reaction to excipient	109	11	71	6	38		
Reaction to food additive	2		1		1		

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Reaction to preservatives	17	2	9	2	8	2	2
Reaction to sweetener	1			1	1		
Rubber sensitivity	8		3	2	5		
Sarcoidosis	203	87	203			3	3
Seasonal allergy	501	30	118	96	383	3	4
Selective IgA immunodeficiency	4	1	2		2		
Selective IgG subclass deficiency	1		1				
Sensitisation	60	3	15	10	45		
Serum sickness	34	3	19	4	15		
Serum sickness-like reaction	12	2	8		4		
Smoke sensitivity	3		1		2		
Solid organ transplant rejection	1		1				
Sunscreen sensitivity	1		1				
Systemic immune activation	8	2	8				
Transplant rejection	27	13	27				
Type I hypersensitivity	205	29	205				1
Type II hypersensitivity	4		4				
Type III immune complex mediated reaction	25	6	25				
Type IV hypersensitivity reaction	119	7	38	14	81	1	1
Vaccine associated enhanced disease	22	12	22				
Vaccine associated enhanced respiratory disease	9	9	9				
Total:	31895	3108	16159	6769	15736	104	180

System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal abscess	14	8	14				
Abdominal infection	19	4	19				
Abdominal sepsis	5	2	5				
Abdominal wall abscess	3	1	3				
Abortion infected	1		1				
Abscess	234	28	96	48	138	4	5
Abscess bacterial	5		4		1		
Abscess fungal	1	1	1				
Abscess intestinal	7	3	7			1	1
Abscess jaw	4	1	4				
Abscess limb	52	7	29	10	23		2
Abscess neck	10	3	8	1	2		
Abscess of external auditory meatus	1		1				
Abscess of eyelid	3		2	1	1		
Abscess of salivary gland	3		3				
Abscess oral	22		8	3	14		
Abscess rupture	3		2	1	1		
Abscess soft tissue	1				1		
Abscess sweat gland	1				1		
Acanthamoeba keratitis	2		2				
Acariasis	2		2				
Acarodermatitis	32	5	13	6	19		
Achromobacter infection	1	1	1				
Acinetobacter bacteraemia	1	1	1				
Acinetobacter infection	2	1	2				
Acne pustular	12		3	2	9		
Acquired immunodeficiency syndrome	4	1	4				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acrodermatitis chronica atrophicans	1			1	1		
Actinomycosis	1	1	1				
Acute endocarditis	2		2				
Acute haemorrhagic conjunctivitis	2		1		1		
Acute hepatitis B	1		1				
Acute HIV infection	1		1				
Acute sinusitis	43	7	17	11	26		
Adenopathy syphilitic	4		4				
Adenoviral conjunctivitis	3		1	1	2		
Adenovirus infection	5		2		3		
Adenovirus reactivation	1	1	1				
Administration site abscess	1				1		
Administration site cellulitis	2			2	2		
Adrenalitis	1		1				
Aerococcus urinae infection	3		2		1		
African trypanosomiasis	8	3	8				1
Allergic bronchopulmonary mycosis	1		1				
Alveolar osteitis	4	1	2	1	2		
Amniotic cavity infection	16	1	16				1
Amoebiasis	4	2	3	1	1		
Anal abscess	27	12	27				1
Anal candidiasis	3		1		2		
Anal fungal infection	1			1	1		
Anal infection	2			1	2		
Anorectal infection	1	1	1				
Appendiceal abscess	4	2	4				
Appendicitis	662	242	662			12	17

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Appendicitis perforated	72	29	72			2	2
Application site abscess	1				1		
Application site pustules	2		1	1	1		
Arboviral infection	1		1				
Arteriosclerotic gangrene	1		1				
Arthritis bacterial	26	12	26				
Arthritis gonococcal	1	1	1				
Arthritis infective	25	7	25			1	4
Arthritis viral	3		1	1	2		
Arthropod infestation	1		1				
Aspergillus infection	7	3	7				
Asymptomatic bacteriuria	6	1	3		3		
Asymptomatic COVID-19	1859	498	1779	11	80	18	47
Atypical mycobacterial infection	3	1	3				
Atypical pneumonia	48	8	48			2	3
Babesiosis	2		2				
Bacillus infection	1		1				
Bacteraemia	44	12	44			1	2
Bacterial colitis	2	1	2				
Bacterial diarrhoea	4		4				
Bacterial disease carrier	4	2	4				
Bacterial infection	173	21	97	29	76	2	2
Bacterial parotitis	1		1				
Bacterial pericarditis	2	1	2				
Bacterial prostatitis	4	3	4				
Bacterial pyelonephritis	2		2				
Bacterial rhinitis	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bacterial sepsis	17	4	17				
Bacterial translocation	1	1	1				
Bacterial vaginosis	44	5	8	19	36		
Bacteriuria	7		4		3		
Bacteroides bacteraemia	2	1	2				
Balanitis candida	2	1	2				
Bartholinitis	10	2	4	3	6		
Bartholin's abscess	6	2	4		2		
Bed bug infestation	2		1		1		
Beta haemolytic streptococcal infection	16	6	16			1	1
Biliary sepsis	5		5				
Biliary tract infection	3	1	3				
Blastocystis infection	2		2				
Blister infected	24	3	6	3	18		1
Body tinea	12	1	1	4	11		
Bone abscess	3		3				
Bone tuberculosis	2	1	2				
Borrelia infection	32	11	32				
Brain abscess	11	7	11				
Brain empyema	1		1				
Breakthrough COVID-19	54	53	53	1	1	1	1
Breast abscess	42	7	24	4	18		1
Breast cellulitis	3		3				
Breast discharge infected	3		3				
Bronchiolitis	23	9	23				1
Bronchitis	759	88	246	207	513	3	8
Bronchitis bacterial	16	6	16				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bronchitis viral	8	1	3	1	5		
Bronchopulmonary aspergillosis	5	1	5				
Brucellosis	1		1				
Bullous impetigo	4		2		2		
Bursitis infective	4	2	4				
Campylobacter colitis	1		1				
Campylobacter gastroenteritis	11	2	11				
Campylobacter infection	12	2	7	1	5		
Candida infection	166	16	55	25	111		2
Candida sepsis	3		3				
Capnocytophaga sepsis	1	1	1				
Carbuncle	3		1	1	2		
Cardiac infection	83	30	83				
Cardiac valve abscess	1	1	1				
Cardiac valve vegetation	6	2	6				
Catheter site infection	2		2				
Cat scratch disease	3		2		1		
Cavernous sinus thrombosis	5	2	5				
Cellulitis	744	147	744			11	21
Cellulitis gangrenous	2		2				
Cellulitis orbital	5	4	5				
Cellulitis pasteurella	1		1				
Cellulitis staphylococcal	4		4				
Central nervous system fungal infection	1	1	1				
Central nervous system infection	12	6	12				
Central nervous system viral infection	2	2	2				
Cerebral fungal infection	1	1	1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cervicitis	3		2		1		
Cestode infection	1	1	1				
Chlamydial infection	10	5	10				
Cholecystitis infective	17	7	17				
Chorioretinitis	21	6	21				
Chronic active Epstein-Barr virus infection	3	3	3				
Chronic hepatitis C	1	1	1				
Chronic sinusitis	37	8	11	14	26		
Chronic tonsillitis	3	1	3			1	1
Citrobacter infection	3		3				
Clostridial infection	4	1	4				
Clostridium colitis	1		1				
Clostridium difficile colitis	20	8	20			1	1
Clostridium difficile infection	28	9	28			2	5
CNS ventriculitis	2	1	2				
Coccidioidomycosis	4		4				
Colon gangrene	3		3				
Community acquired infection	2	2	2				
Complicated appendicitis	20	6	20				
Conjunctivitis	939	44	179	214	760		1
Conjunctivitis bacterial	20	1	16	2	4		
Conjunctivitis viral	12		3	2	9		
Corneal abscess	2	1	2				
Corneal infection	2		2			1	1
Coronavirus infection	57	9	33	7	24	2	3
Coronavirus pneumonia	10	2	10				
COVID-19	74803	46545	71486	539	3317	900	1209

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
COVID-19 pneumonia	1615	548	1615			9	32
Cow pox	3	3	3				
Coxsackie viral infection	9	2	4	2	5		
Cranial nerve infection	3		3				
Creutzfeldt-Jakob disease	42	22	42				
Croup infectious	16	13	16				
Cryptococcal meningoencephalitis	1		1				
Cryptosporidiosis infection	2		1		1		
Cutaneous mucormycosis	1	1	1				
Cystitis	682	33	191	148	491	1	5
Cystitis bacterial	10	4	8		2		
Cystitis escherichia	9	2	4	2	5		1
Cystitis klebsiella	2		2				
Cystitis viral	1		1				
Cytomegalovirus chorioretinitis	1		1				
Cytomegalovirus colitis	1	1	1				
Cytomegalovirus enterocolitis	1	1	1				
Cytomegalovirus hepatitis	10	2	10				
Cytomegalovirus infection	60	27	60				
Cytomegalovirus infection reactivation	28	8	28				
Cytomegalovirus mononucleosis	2	1	2				
Cytomegalovirus pericarditis	1		1				
Cytomegalovirus syndrome	1		1				
Cytomegalovirus viraemia	7	6	7				
Dacryocanaliculitis	2	1	2				
Dacryocystitis	4	1	4				
Demodicidosis	3	2	2	1	1		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dengue fever	21	6	7	12	14		
Dengue haemorrhagic fever	1	1	1				
Dental fistula	2		2				
Dermatitis infected	24	4	16	2	8		
Dermatophytosis	4	1	1		3		
Dermatophytosis of nail	4			1	4		
Dermo-hypodermitis	24	7	24				
Device related infection	21	6	21			1	1
Device related sepsis	1	1	1				
Diabetic foot infection	2				2		
Diabetic gangrene	1		1				
Diarrhoea infectious	7	2	6	1	1		
Dientamoeba infection	2				2		
Diphtheria	2		2				
Disseminated Bacillus Calmette-Guerin infection	35	2	35				
Disseminated tuberculosis	2	1	2				
Disseminated varicella	1		1				
Disseminated varicella zoster vaccine virus infection	1		1				
Disseminated varicella zoster virus infection	8	2	8				
Diverticulitis	261	90	261				7
Diverticulitis intestinal haemorrhagic	4	1	4				
Diverticulitis intestinal perforated	3	2	3				
Douglas' abscess	1		1				
Dysentery	375	45	375			1	15
Ear infection	559	37	181	106	378	2	4
Ear infection bacterial	4	1	4				
Ear infection fungal	4		1	2	3		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ear infection viral	2		1		1		
Ear lobe infection	2			1	2		
Ear, nose and throat infection	7	1	1	6	6		
Ebola disease	1		1				
Echo virus infection	1	1	1				
Ecthyma	2				2		
Eczema herpeticum	17	5	17				
Eczema impetiginous	3		2	1	1		
Eczema infected	11	3	4	5	7		
Embolic pneumonia	1		1				
Empyema	9	4	9			1	1
Encephalitis	356	113	356				
Encephalitis brain stem	15	8	15				
Encephalitis california	1		1				
Encephalitis enteroviral	1		1				
Encephalitis lethargica	1		1				
Encephalitis meningococcal	2	2	2				
Encephalitis viral	28	7	28				
Encephalomyelitis	30	14	30				
Encephalomyelitis viral	1		1				
Endocarditis	122	42	122			2	3
Endocarditis bacterial	6		6				
Endocarditis haemophilus	1		1				
Endocarditis staphylococcal	3	2	3				
Endometritis	16	7	16				
Endometritis decidual	1	1	1				
Endophthalmitis	3	2	3				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Endotoxic shock	1		1				
Enteritis infectious	16	2	16				1
Enterobacter bacteraemia	1		1				
Enterobacter infection	6	3	6				
Enterobacter sepsis	1		1				
Enterobiasis	2				2		
Enterococcal bacteraemia	1	1	1				
Enterococcal infection	19	5	19				
Enterococcal sepsis	1		1				
Enterocolitis infectious	1	1	1				
Enterocolitis viral	1		1				
Enterovirus infection	4	1	4				
Epidemic polyarthritis	1			1	1		
Epididymitis	77	35	77			1	2
Epiglottitis	18	5	18				
Epstein-Barr viraemia	12		2	5	10		
Epstein-Barr virus infection	128	25	60	43	68	1	1
Epstein-Barr virus infection reactivation	133	67	133				
Erysipelas	351	105	351			2	5
Erysipeloid	3	1	2	1	1		
Erythema induratum	10	2	10				1
Erythema infectiosum	1				1		
Erythema migrans	18	1	5	6	13		
Erythrasma	3	1	3				
Escherichia bacteraemia	13	4	13				
Escherichia infection	28	4	26	1	2		
Escherichia pyelonephritis	5	1	5				

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Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Escherichia sepsis	14	1	14			1	2
Escherichia urinary tract infection	49	7	43	3	6		
Exanthema subitum	3				3		
External ear cellulitis	3		3				1
Extradural abscess	2	1	2				1
Eye abscess	6	2	6				
Eye infection	178	18	56	47	122		
Eye infection bacterial	5	1	3	2	2		
Eye infection intraocular	2		2				
Eye infection staphylococcal							1
Eye infection toxoplasmal	2	1	2				
Eye infection viral	7		1	3	6	1	1
Eyelid boil	2		2				
Eyelid infection	25	2	4	4	21		
Fallopian tube abscess	1	1	1				
Fascial infection	1		1				
Fasciolopsiasis	2		2				
Febrile infection	21	2	13	2	8		
Focal peritonitis	4	1	4				
Folliculitis	113	11	37	24	76	1	1
Foot and mouth disease	2				2		
Fournier's gangrene	2	1	2				
Fungaemia	3	2	3				
Fungal balanitis	1			1	1		
Fungal disease carrier	2			2	2		
Fungal foot infection	6			4	6		
Fungal infection	220	17	39	74	181	2	2

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Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Fungal oesophagitis	1		1				
Fungal peritonitis	1		1				
Fungal rhinitis							1
Fungal skin infection	48	3	11	12	37	1	2
Funguria	1		1				
Funisitis	5		5				
Furuncle	232	17	57	62	175	1	3
Gangrene	24	13	24				
Gas gangrene	1		1				
Gastric infection	9	1	9			1	1
Gastric ulcer helicobacter	1		1				
Gastritis bacterial	3		3				
Gastritis herpes	1		1				
Gastroenteritis	444	40	150	107	294	3	4
Gastroenteritis adenovirus	1		1				
Gastroenteritis bacterial	6		5	1	1		
Gastroenteritis Escherichia coli	3	1	3				
Gastroenteritis norovirus	3		3				
Gastroenteritis rotavirus	2		2				
Gastroenteritis salmonella	1	1	1				
Gastroenteritis viral	122	10	42	19	80		1
Gastrointestinal bacterial infection	2		1	1	1		
Gastrointestinal bacterial overgrowth	6	1	5		1		
Gastrointestinal candidiasis	4	2	4				
Gastrointestinal fungal infection	3	3	3			1	1
Gastrointestinal infection	34	10	16	8	18		
Gastrointestinal viral infection	7	1	5	1	2		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Genital abscess	10	4	10				
Genital candidiasis	3		1	1	2		
Genital herpes	430	31	128	130	302	1	2
Genital herpes simplex	26	2	7	3	19		
Genital herpes zoster	35	3	18	7	17		
Genital infection	4	2	2	2	2		
Genital infection female	5			5	5		
Genital infection fungal	12	1	3	3	9		
Genital infection viral	3		2		1		
Genital ulcer syndrome	2				2		
Genitourinary tract infection	4		2	2	2		
Gianotti-Crosti syndrome	9	2	3	4	6		
Gingival abscess	15	3	6	2	9		
Gingivitis	260	19	43	69	217		
Gonorrhoea	3	1	3				
Groin abscess	11	5	11				
Groin infection	4	1	2	1	2		
H1N1 influenza	1				1		
H3N2 influenza	2			1	2		
Haematoma infection	3		3				
Haemophilus infection	5	3	5				
Haemorrhagic fever with renal syndrome	1		1				
Haemorrhagic pneumonia	4	1	4				
Haemorrhagic varicella syndrome	1		1				
Haemorrhoid infection	2		1	1	1		
Hand-foot-and-mouth disease	15	1	2	7	13		
Helicobacter gastritis	3	1	2		1		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Helicobacter infection	33	3	20	9	13	1	1
Helminthic infection	4	3	4				
Hepatic cyst infection	2		2				
Hepatic infection	2	1	2				
Hepatitis A	7	1	3	2	4		
Hepatitis B	13	1	13				
Hepatitis B reactivation	3	1	3				
Hepatitis C	14	5	14				
Hepatitis D	1		1				
Hepatitis E	15	7	15				
Hepatitis infectious mononucleosis	7	3	7				
Hepatitis viral	14	3	14				
Herpangina	4		1		3		
Herpes dermatitis	43	7	19	6	24		
Herpes ophthalmic	168	71	168				
Herpes pharyngitis	5		5				
Herpes sepsis	2		2				
Herpes simplex	602	28	107	176	495	1	2
Herpes simplex encephalitis	16	3	16				
Herpes simplex gastritis	1		1				
Herpes simplex hepatitis	3		3				
Herpes simplex meningitis	3	1	3				
Herpes simplex meningoencephalitis	4	3	4				
Herpes simplex otitis externa	2				2		
Herpes simplex pharyngitis	1		1				
Herpes simplex reactivation	87	7	18	17	69		
Herpes simplex viraemia	1		1				

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Herpes virus infection	658	44	114	252	544		2
Herpes zoster	18744	1028	4243	5194	14501	11	30
Herpes zoster cutaneous disseminated	40	7	40				
Herpes zoster disseminated	23	9	23				
Herpes zoster infection neurological	24	4	24				
Herpes zoster meningitis	53	20	53				
Herpes zoster meningoencephalitis	26	4	26			1	1
Herpes zoster meningomyelitis	1		1				
Herpes zoster meningoradiculitis	6		6				
Herpes zoster necrotising retinopathy	1		1				
Herpes zoster oticus	196	60	196			1	2
Herpes zoster pharyngitis	2	1	2				
Herpes zoster reactivation	186	25	65	34	121		
Herpetic radiculopathy	2			2	2		
HIV infection	8	4	8				
HIV peripheral neuropathy	1	1	1				
Hookworm infection	2		2				
Hordeolum	202	12	46	47	156		
HTLV-1 carrier	1	1	1				
Human ehrlichiosis	1	1	1				
Human herpesvirus 6 encephalitis	1		1				
Human herpesvirus 6 infection	6		5		1		
Human herpesvirus 6 infection reactivation	2		2				
Human herpesvirus 7 infection	1		1				
Hypopyon	1		1				
Iatrogenic infection	2				2		
Ileal gangrene	2	1	2				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Immune reconstitution inflammatory syndrome associated tu	1		1				
Impetigo	74	5	26	17	48		
Implant site infection	2	1	2				
Incision site abscess	1		1				
Indeterminate leprosy	1		1				
Infected bite	12	1	8	2	4		
Infected bunion	1	1	1				
Infected cyst	13	2	11	2	2		
Infected dermal cyst	6		3	1	3		
Infected fistula	1	1	1				
Infected lymphocele	2		2				
Infected seroma	3		3				
Infected skin ulcer	8	2	8				
Infected vasculitis	1	1	1				
Infection	1139	153	623	157	516	8	17
Infection in an immunocompromised host	7	2	7				
Infection parasitic	10	3	3	2	7		
Infection protozoal	1	1	1				
Infection reactivation	19	2	8	5	11		
Infection susceptibility increased	189	30	61	123	128	3	3
Infection via vaccinee	1		1				
Infectious disease carrier	2		1		1		
Infectious mononucleosis	214	27	91	58	123	1	1
Infectious pleural effusion	14	6	14				
Infectious thyroiditis	11	1	3	6	8		
Infective aneurysm	1		1				
Infective chondritis	1	1	1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Infective exacerbation of bronchiectasis	2		2				
Infective exacerbation of chronic obstructive airways disease	8		8				
Infective glossitis	6			2	6		
Infective myositis	2		2				
Infective pericardial effusion	4	2	4				
Infective tenosynovitis	4	2	4				
Infective uveitis	1		1				
Infestation	1		1				
Influenza	15464	389	1882	7256	13582	8	35
Infusion site infection	1		1				
Injection site abscess	2	1	1	1	1		
Injection site cellulitis	6		1	1	5		
Injection site infection	11			1	11		
Injection site pustule	1		1				
Intervertebral discitis	27	8	27				
Intestinal gangrene	1		1				
Intestinal tuberculosis	1	1	1				
Intrauterine infection	4	1	4				
Janeway lesion	1			1	1		
Japanese spotted fever	1		1				
Joint abscess	2		2				
Keratitis bacterial	1		1				
Keratitis viral	2	2	2				
Keratouveitis	5	3	5				
Kidney infection	166	47	166			1	1
Klebsiella bacteraemia	2		2				
Klebsiella infection	31	8	28	2	3		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Klebsiella sepsis	2		2				
Labyrinthitis	272	36	156	32	116	1	3
Lactobacillus infection	1		1				
Large intestine infection	17	2	11	5	6		1
Laryngitis	250	19	66	57	184	1	2
Laryngitis bacterial	1		1				
Laryngitis viral	2			2	2		
Laryngopharyngitis	9	1	2	3	7		
Latent tuberculosis	2		1	1	1		
Legionella infection	6	2	6				
Lemierre syndrome	1	1	1				
Lepromatous leprosy	1	1	1				
Leprosy	2	2	2				
Leptospirosis	1	1	1				
Lice infestation	4	1	2	1	2		
Lip infection	1				1		
Listeriosis	3		3				
Liver abscess	20	9	20				
Localised infection	162	23	83	25	79	5	6
Lochial infection	1		1				
Lower respiratory tract infection	567	98	476	69	91	1	5
Lower respiratory tract infection bacterial	3		3				
Lower respiratory tract infection viral	3		3				
Ludwig angina	3	2	3				
Lung abscess	6	1	6				
Lyme carditis	3		3				
Lyme disease	118	37	118			1	1

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lymphadenitis bacterial	5	1	5				
Lymphadenitis viral	2		2				
Lymphangitis	149	45	148	1	1	2	4
Lymph gland infection	44	8	24	4	20		
Lymph node abscess	38	11	38				
Lymph node tuberculosis	2		2				
Malaria	6	1	6				
Malaria recrudescence	2	2	2				
Malaria relapse	2	2	2				
Mastitis	420	34	290	105	130	1	5
Mastitis bacterial	3	1	3				
Mastitis postpartum	16	2	2	13	14		
Mastoiditis	19	9	19			1	1
Measles	27	11	27				
Measles post vaccine	2	1	2				
Mediastinitis	2	1	2				
Medical device site abscess	1			1	1		
Meningitis	213	79	213			1	1
Meningitis aseptic	128	38	128			1	1
Meningitis bacterial	24	6	24				
Meningitis coxsackie viral	1		1				
Meningitis herpes	9	1	9				
Meningitis meningococcal	1	1	1				
Meningitis neonatal						1	1
Meningitis pneumococcal	7	1	7				
Meningitis staphylococcal	1		1				
Meningitis tuberculous	2		2				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Meningitis viral	63	23	63				
Meningococcal bacteraemia	1		1				
Meningococcal infection	2	1	2				
Meningoencephalitis bacterial	3		3				
Meningoencephalitis herpetic	45	20	45				
Meningoencephalitis viral	8	1	8				
Meningomyelitis herpes	2		2				
Metapneumovirus infection	1				1		
Microsporum infection	1			1	1		
Middle East respiratory syndrome	4		4				
Molluscum contagiosum	9		1	5	8		
Mononucleosis syndrome	7		3	2	4		
Moraxella infection	1		1				
Morganella infection	6	1	6				
Mucormycosis	1		1				
Mucosal infection	3		1		2		
Mumps	28	1	11	5	17		
Muscle abscess	5	1	5				
Mycobacterial infection	3	2	3				
Mycobacterium avium complex infection	1		1				
Mycoplasma infection	6	3	4	1	2		
Mycotoxicosis	1	1	1				
Myelitis	373	140	373				1
Myocarditis bacterial	1	1	1				
Myocarditis infectious	7	2	7				
Myocarditis mycotic	2	2	2				
Myocarditis septic	5	2	5				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Myringitis	8	1	5	3	3		
Nail bed infection	1			1	1		
Nail infection	5		2	1	3		
Nasal abscess	6	1	6				
Nasal herpes	108	6	18	30	90		
Nasal vestibulitis	20	2	3	9	17	1	1
Nasopharyngitis	8768	373	1508	2522	7260	21	46
Necrotising fasciitis	18	7	18				
Necrotising soft tissue infection	1	1	1				
Necrotising ulcerative gingivostomatitis	3	3	3				
Necrotising ulcerative periodontitis						1	1
Nematodiasis	1	1	1				
Neonatal infection	2	1	2				
Neonatal pneumonia							1
Neovaginal infection	1			1	1		
Nephritis bacterial	1	1	1				
Neuroborreliosis	19	9	19			2	2
Neurological infection	2		2				
Neutropenic sepsis	5	1	5				
Nipple infection	4	1	1	1	3		
Norovirus infection	9	2	2	3	7		
Nosocomial infection	8	4	6	2	2		
Oesophageal candidiasis	8	4	8				
Oesophageal infection	1		1				
Omphalitis	7	5	7			1	1
Onychomycosis	18	2	4	8	14		1
Oophoritis	5	3	5				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ophthalmia neonatorum	1	1	1				
Ophthalmic herpes simplex	32	9	32				
Ophthalmic herpes zoster	701	222	701			2	3
Opportunistic infection	2		2				
Oral bacterial infection	1		1				
Oral candidiasis	156	12	47	33	109		1
Oral fungal infection	71	4	17	17	54		
Oral herpes	2784	97	367	693	2417	4	9
Oral herpes zoster	2			2	2		
Oral infection	25	2	8	6	17		
Oral pustule	13	2	3	5	10		
Oral viral infection	4		1		3		
Orbital infection	1	1	1				
Orchitis	56	9	31	12	25		
Orf	1				1		
Oropharyngeal candidiasis	9	3	5		4		
Oropharyngitis fungal						1	1
Osteomyelitis	42	16	42				1
Osteomyelitis acute	3	2	3				
Osteomyelitis bacterial	1		1				
Osteomyelitis chronic	3	3	3				
Otitis externa	77	10	26	13	51		
Otitis externa bacterial	1	1	1				
Otitis externa fungal	2			1	2		
Otitis media	101	8	32	23	69		
Otitis media acute	24	4	6	5	18		
Otitis media bacterial	1				1		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Otitis media chronic	16	6	12		4		
Otosalpingitis	6		1	3	5		
Ovarian abscess	3	3	3				
Ovarian bacterial infection	1	1	1				
Overgrowth bacterial	1		1				
Pancreas infection	5	2	5				
Pancreatic abscess	1	1	1				
Papilloma viral infection	25	6	11	11	14		
Paragonimiasis	3	3	3				
Parainfluenzae viral laryngotracheobronchitis	1		1				
Parainfluenzae virus infection	7		6		1		
Paranasal sinus abscess	1	1	1				
Parapharyngeal space infection	2	1	2				
Parasite allergy	1			1	1		
Parasitic gastroenteritis	4	1	4				
Paronychia	28	5	8	8	20		
Parotid abscess	1	1	1				
Parotitis	142	11	43	39	99		
Parvovirus B19 infection	5	1	4		1		
Parvovirus infection	2	1	1		1		
Pathogen resistance	8	3	8				
Pelvic abscess	1	1	1				
Pelvic infection	3	1	3				
Pelvic inflammatory disease	35	15	35				
Penile abscess	1		1				
Peptostreptococcus infection	1	1	1				
Pericarditis infective	17	5	17				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pericarditis tuberculous	1		1				
Perichondritis	15	3	9	2	6		
Pericoronitis	3	1	2		1		
Perihepatitis	1	1	1				
Perineal abscess	2	1	2				
Perineal cellulitis	1	1	1				
Periodontitis	29		4	15	25		
Periorbital abscess	1		1				
Periorbital cellulitis	10	4	10				
Periorbital infection	1		1				
Perirectal abscess	1	1	1				
Peritonitis	84	26	84			1	2
Peritonitis bacterial	5	2	5				
Peritonsillar abscess	37	10	37			1	1
Peritonsillitis	1		1				
Periumbilical abscess	1		1				
Persistent generalised lymphadenopathy	5	2	4	1	1		
Pertussis	21	7	21				
Pharyngeal abscess	13	2	13				
Pharyngeal pustule	3			2	3		
Pharyngitis	520	32	124	146	396	1	2
Pharyngitis bacterial	10	2	8	1	2		
Pharyngitis streptococcal	71	5	17	6	54	1	1
Pharyngotonsillitis	12	2	8	2	4		
Phlebitis infective	1	1	1				
Picornavirus infection	2				2		
Pilonidal disease	8		1	4	7		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Plague	1		1				
Plasmodium vivax infection	1	1	1				
Pleural infection	2		2				
Pleurisy bacterial	1	1	1				
Pleurisy viral	5	1	5				
Pneumococcal bacteraemia	1		1				
Pneumococcal infection	9	2	9				
Pneumococcal sepsis	4	3	4				
Pneumocystis jirovecii infection	3	2	3				
Pneumocystis jirovecii pneumonia	14	4	14				
Pneumonia	2865	768	2865			38	71
Pneumonia aspiration	296	48	296				
Pneumonia bacterial	113	24	113			2	2
Pneumonia chlamydial	6	2	6				
Pneumonia cytomegaloviral	1		1				
Pneumonia escherichia	1		1				
Pneumonia fungal	5		5				
Pneumonia haemophilus	2	1	2				
Pneumonia klebsiella	20	10	20				
Pneumonia legionella	5	1	5			2	2
Pneumonia moraxella	1		1				
Pneumonia mycoplasmal	10	3	10				
Pneumonia pneumococcal	23	4	23				
Pneumonia proteus	1	1	1				
Pneumonia pseudomonal	7	4	7				
Pneumonia respiratory syncytial viral	1		1				
Pneumonia staphylococcal	13	3	13				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pneumonia streptococcal	8	4	8				
Pneumonia viral	36	6	36			2	2
Poliomyelitis	2	1	2				
Polyomavirus viraemia	1	1	1				
Post-acute COVID-19 syndrome	296	93	147	107	149		1
Postoperative wound infection	8	2	8				
Post procedural infection	6		1	1	5		2
Post treatment Lyme disease syndrome	2	1	2				
Post viral fatigue syndrome	237	66	178	25	59		1
Prion disease	5	2	5				
Proctitis herpes	2				2		
Progressive multifocal leukoencephalopathy	2		2				
Propionibacterium infection	1	1	1				
Prostate infection	10	3	10				
Prostatic abscess	2	1	2				
Proteus infection	3	1	3				
Pseudomembranous colitis	5	2	5				
Pseudomonal bacteraemia	2		2				
Pseudomonal sepsis	3	1	3				
Pseudomonas infection	16	7	16				
Psittacosis	1			1	1		
Psoas abscess	3		3				
Puerperal pyrexia	1		1			1	1
Pulmonary sepsis	17	2	17				
Pulmonary tuberculoma	1	1	1				
Pulmonary tuberculosis	27	23	27				
Pulpitis dental	89	12	23	27	66		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Puncture site infection	1	1	1				
Purple urine bag syndrome	1				1		
Purulence	30	5	9	11	21		
Purulent discharge	34	3	14	14	20		
Purulent pericarditis	2	2	2				
Pustule	428	20	64	156	364		1
Pyelitis	17	4	17				1
Pyelonephritis	197	80	197			5	7
Pyelonephritis acute	35	12	35				
Pyelonephritis fungal	1	1	1				
Pyoderma	4	1	4				
Pyoderma streptococcal	1		1				
Pyometra	1	1	1				
Pyomyositis	1		1				
Pyuria	10	4	6	1	4		
Q fever	35	6	35			3	4
Raoultella ornithinolytica infection	1		1				
Rash pustular	225	18	53	48	172		
Rectal abscess	3		3				
Relapsing fever	17	10	17				
Renal abscess	7	2	7				1
Renal graft infection	1		1				
Respiratory moniliasis	1		1				
Respiratory syncytial virus bronchitis	1				1		
Respiratory syncytial virus infection	13	2	6	2	7		
Respiratory tract chlamydial infection	2	1	1	1	1		
Respiratory tract infection	238	26	161	68	77	1	6

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Respiratory tract infection bacterial	6		4	2	2		
Respiratory tract infection viral	11		2	1	9		
Retinitis	13	7	13				
Retroperitoneal abscess	1	1	1				
Rhinitis	1196	57	211	289	985		12
Rhinolaryngitis	2				2		
Rhinotracheitis	2			1	2		
Rhinovirus infection	18	2	8		10		
Rickettsiosis	1	1	1				
Rocky mountain spotted fever	1		1				
Root canal infection	6	1	1	1	5		1
Roseola	8		1	3	7		
Rotavirus infection	2		1		1		
Rubella	9		4	1	5		
Rubella in pregnancy	1		1				
Salmonella sepsis	3		3				
Salmonellosis	5	1	5			1	2
Salpingitis	4	3	4				
Salpingo-oophoritis	2	2	2				
SARS-CoV-2 sepsis	2		2				
Scarlet fever	9	1	5	2	4		1
Scrotal abscess	1	1	1				
Scrotal cellulitis	1		1				
Scrotal infection	2		2				
Scrub typhus	3	1	3				
Sebaceous gland infection	2				2		
Secondary syphilis	3	1	3				

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Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Secondary transmission	4		3		1		
Seminal vesicular infection	1	1	1				
Sepsis	612	169	612			4	5
Sepsis neonatal	3	1	3				
Sepsis syndrome	4	1	4				
Septic arthritis staphylococcal	6	3	6				
Septic coagulopathy	1	1	1				
Septic embolus	4	1	4				
Septic encephalopathy	4	2	4				
Septic pulmonary embolism	1		1				
Septic rash	4	2	4				
Septic shock	239	64	239				
Serratia infection	3		3				
Severe acute respiratory syndrome	33	8	33				
Severe asthma with fungal sensitisation	2	2	2				
Severe fever with thrombocytopenia syndrome	2	1	2				
Severe invasive streptococcal infection	2		2				
Sialoadenitis	49	11	49				
Sinobronchitis	1		1				
Sinusitis	1322	103	360	332	962	4	10
Sinusitis bacterial	10	3	10				
Sinusitis fungal	1				1		
Skin bacterial infection	16	3	6	2	10		
Skin candida	6		2	1	4		
Skin infection	116	15	49	19	67	1	2
Small intestine gangrene	1	1	1				
Smallpox	6	6	6				

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Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Soft tissue infection	21	3	18	2	3	1	1
Spinal cord abscess	4	2	4				
Spinal cord infection	7	3	7				
Splenic infection	2		2				
Sputum purulent	16	1	14	2	2		
Staphylococcal abscess	3	1	1		2		
Staphylococcal bacteraemia	26	3	26				
Staphylococcal impetigo	2		1		1		
Staphylococcal infection	93	16	75	14	18	1	3
Staphylococcal scalded skin syndrome	3	2	3				
Staphylococcal sepsis	17	5	17				
Staphylococcal skin infection	4		2	1	2		
Stenotrophomonas bacteraemia	1		1				
Sternitis	4	1	4				
Streptobacillus infection	4	1	4				
Streptococcal abscess	2	1	2				
Streptococcal bacteraemia	3	2	3				
Streptococcal endocarditis	1		1				
Streptococcal infection	47	7	22	5	25		
Streptococcal sepsis	10	2	10			1	1
Streptococcal urinary tract infection	7	1	7				
Strongyloidiasis	1				1		
Stump appendicitis	1	1	1				
Subacute endocarditis	1		1				
Subacute sclerosing panencephalitis	2	1	2				
Subcutaneous abscess	93	14	40	25	53	1	1
Subdural abscess	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Subglottic laryngitis	5			4	5		
Subperiosteal abscess	1		1				
Superinfection	31	5	20	6	11		
Superinfection bacterial	34	5	34				
Superinfection viral	1		1				
Suspected COVID-19	5748	2715	5042	101	706	185	261
Sweat gland infection	1		1				
Sweating fever	149	25	140	7	9		1
Syphilis	15	7	15				
Syphilis genital	1		1				
Systemic bacterial infection	1		1				
Systemic candida	3	2	3				
Systemic infection	4	1	4				
Systemic viral infection	3	2	3				
Testicular abscess	2		2				
Tetanus	7	4	7				
Thrombophlebitis septic	2	1	2				
Tinea capitis	3			2	3		
Tinea infection	11		1	4	10		
Tinea pedis	20	1	5	7	15		
Tinea versicolour	17		1	5	16		
Tongue abscess	3	2	3				
Tongue fungal infection	8		2	2	6		
Tonsillitis	592	59	191	165	401	2	4
Tonsillitis bacterial	30	3	25	4	5		
Tonsillitis streptococcal	7		6	1	1		
Tooth abscess	80	1	21	20	59		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tooth infection	89	6	24	12	65	2	2
Toxic shock syndrome	10		10				
Toxic shock syndrome streptococcal	1		1				
Toxocariasis	3		3				
Toxoplasmosis	15	2	3	6	12		
Tracheitis	67	3	15	12	52		
Tracheobronchitis	4	1	2	1	2		
Tracheobronchitis bacterial	4	1	4				
Tracheostomy infection	1		1				
Trematode infection	1	1	1				
Trichophytosis	1			1	1		
Tropical spastic paresis	1	1	1				
Tuberculoma of central nervous system	1		1				
Tuberculosis	28	12	28			3	3
Tuberculosis of central nervous system	1		1				
Tuberculous pleurisy	1		1				
Tularaemia	2		2				
Type 2 lepra reaction	2	2	2				
Typhoid fever	2		2				
Upper aerodigestive tract infection	1			1	1		
Upper respiratory tract infection	209	26	77	35	132	1	1
Upper respiratory tract infection bacterial	1			1	1		
Ureaplasma infection	3			2	3		
Ureteritis	3	2	3				
Urethritis	16	2	6	9	10		
Urinary tract candidiasis	4	1	3		1		
Urinary tract infection	1718	159	773	292	945	4	13

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Urinary tract infection bacterial	58	10	43	7	15		
Urinary tract infection enterococcal	4		4				
Urinary tract infection fungal	4	1	4				
Urinary tract infection pseudomonal	1		1				
Urinary tract infection staphylococcal	3	3	3				
Urogenital infection bacterial	2	1	2				
Urosepsis	82	21	82			1	2
Uterine abscess	1		1				
Uterine infection	8	3	8				
Vaccination site abscess	128	11	38	35	90	1	1
Vaccination site cellulitis	197	15	113	14	84		
Vaccination site infection	150	6	37	20	113		
Vaccination site joint infection	1		1				
Vaccination site pustule	49		6	14	43		
Vaccine associated paralytic poliomyelitis	1		1				
Vaccine bacteria shedding	1		1				
Vaccine breakthrough infection	110	64	98	12	12		
Vaccine virus shedding	1				1		
Vaccinia virus infection	2	1	2				
Vaginal abscess	3	1	3				
Vaginal infection	67	4	11	19	56		
Vaginitis gardnerella	3			3	3		
Variant Creutzfeldt-Jakob disease	1		1				
Varicella	179	17	48	40	131		
Varicella encephalitis	1	1	1				
Varicella post vaccine	3			2	3		
Varicella zoster oesophagitis	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Varicella zoster pneumonia	2		2				
Varicella zoster virus infection	110	19	52	18	58		
Vascular device infection	4	2	4				
Vestibular neuronitis	566	182	507	1	59	2	2
Vestibulitis	8		4		4		
Viraemia	2			1	2		
Viral corneal ulcer	1		1				
Viral diarrhoea	3		1		2		1
Viral infection	424	47	191	84	233	2	3
Viral keratouveitis	2	1	2				
Viral labyrinthitis	11		4		7		
Viral myelitis	3		3				
Viral myocarditis	48	16	48				
Viral myositis	2	2	2				
Viral parotitis	1			1	1		
Viral pericarditis	48	13	48				
Viral pharyngitis	43	4	21	10	22		
Viral rash	97	7	33	11	64		
Viral rhinitis	1				1		
Viral sepsis	3		3				
Viral sinusitis	2		1		1		
Viral skin infection	3		1	1	2		
Viral tonsillitis	5		2		3		
Viral upper respiratory tract infection	14	1	5	3	9		
Viral uveitis	1		1				
Viral vasculitis	1		1				
Virologic failure	3		1	1	2		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Visceral leishmaniasis	1	1	1				
Vulval abscess	4	1	4				
Vulvitis	11	1	4	3	7		
Vulvovaginal candidiasis	128	9	39	21	89		
Vulvovaginal mycotic infection	197	6	16	81	181		
Vulvovaginitis	4	1	3	1	1		
Waterhouse-Friderichsen syndrome	1	1	1				
West Nile viral infection	1	1	1				
Wound abscess	3		1	1	2		
Wound infection	21	2	17	3	4		3
Wound infection bacterial	1		1				
Wound infection fungal							1
Wound infection staphylococcal	6	3	6				
Wound sepsis	1		1				1
Yellow fever	1		1				
Yersinia bacteraemia	1		1				
Yersinia infection	6	4	6				
Zoonotic bacterial infection	2	1	2				
Total:	167382	58810	110562	21755	56820	1360	2089

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal injury	3	1	2		1		
Abdominal wall wound	1			1	1		
Abortion induced incomplete	1		1				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Accident	57	6	31	6	26		
Accidental exposure to product	198	1	7	26	191		1
Accidental exposure to product by child	3		1		2		
Accidental overdose	319	9	23	72	296		
Accidental underdose	33			13	33		
Accident at home	5	1	2		3		
Accident at work	4	2	2	1	2	1	1
Acetabulum fracture	3	1	3				
Administration related reaction	1			1	1		
Adrenal gland injury	1			1	1		
Adverse event following immunisation	225	27	47	161	178		
Airway burns	7		3		4		
Airway complication of anaesthesia	2		2				
Alcohol poisoning	11	4	11			1	1
Anaemia postoperative	2		1		1		
Anaesthetic complication	3		1	1	2		
Anaesthetic complication neurological	1	1	1				
Anal injury	1		1				
Anastomotic complication	1		1				
Anastomotic leak	1	1	1				
Anastomotic ulcer	1		1				
Animal bite	42		3	18	39		
Animal scratch	6			3	6		
Ankle fracture	26	8	22	3	4	1	2
Anterior cord syndrome	2	1	2				
Arterial injury	8	4	8				
Arteriovenous fistula site complication	1		1				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Arteriovenous fistula site haemorrhage	1	1	1				
Arteriovenous fistula thrombosis	8	1	8				
Arteriovenous graft thrombosis	1		1				
Arthropod bite	144	6	33	27	111		
Arthropod sting	61	2	5	13	56	1	1
Asbestosis	1			1	1		
Atypical femur fracture	2		2				
Auricular haematoma	1		1				
Autonomic dysreflexia	8		8				
Axillary nerve injury	8	4	8				
Axillary web syndrome	14	1	4	3	10		
Back injury	49	7	23	6	26		2
Barotitis media	2				2		
Barotrauma	9	3	3	2	6		
Bite	27		6	3	21		
Bladder injury	5		2	3	3		
Bone contusion	27	5	14	6	13		1
Bone fissure	5		1	1	4		
Bone fragmentation	2	1	2				
Booster dose missed	11			3	11		
Brachial plexus injury	16	5	11	3	5		
Brain contusion	22	8	22				
Brain herniation	34	7	34				
Breast injury	5	4	5				
Bronchial injury	1		1				
Burn oesophageal	19	2	6	1	13		
Burn of internal organs	9	1	6		3		

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System Organ Class

Injury, poisoning and procedural complications

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Burn oral cavity	22	5	22				
Burns first degree	1				1		
Burns second degree	26	2	10	3	16		
Burns third degree	10	3	10				
Bursa injury	6	1	3		3		
Buttock injury	3			1	3		
Carbon monoxide poisoning	1		1				
Cardiac contusion	2	2	2				
Cardiac herniation	1	1	1				
Cardiac procedure complication	4	2	4				
Cardiac valve rupture	1		1				
Cardiac vein dissection	1	1	1				
Cardiac vein perforation	1	1	1				
Cartilage injury	12	2	8	1	4	1	1
Central cord syndrome	1		1				
Central nervous system injury	3		1	1	2		
Cerebral hyperperfusion syndrome	3		3				
Cerebral ventricle collapse	6		6				
Cervical vertebral fracture	4	1	4			1	1
Cervix injury	1	1	1				
Chemical burn	5			1	5		
Chemical burn of skin	7	1	4	1	3		
Chemical cystitis	2				2		
Chemical poisoning	1	1	1				
Chest crushing	23	7	23				
Chest injury	37	3	37				2
Chillblains	312	25	71	78	241		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chloracne	1			1	1		
Circumstance or information capable of leading to device use	8			1	8		
Circumstance or information capable of leading to medicatio	495	2	3	69	492		
Clavicle fracture	33	9	23	2	10		2
Cold burn	5		1	2	4		
Cold shock response	2		1	1	1		
Colon injury	4		1	1	3	1	1
Comminuted fracture	2	1	2				
Complications of transplanted kidney	2		2				
Compression fracture	11	3	10	1	1		
Concussion	153	21	83	23	70	1	2
Conjunctival laceration	1				1		
Contraindicated product administered	20	1	7	3	13		
Contraindicated product prescribed	3		1		2		
Contusion	5286	359	1504	1076	3782	5	18
Corneal abrasion	10	3	4	3	6		
Corneal laceration	1	1	1				
Coronary bypass thrombosis	1		1				
Counterfeit product administered	16			4	16		
Cranial nerve injury	4	1	4				
Craniocerebral injury	63	12	63				1
Craniofacial fracture	1		1				
Craniofacial injury	4	1	3		1		
Crush injury	3		3				
Deafness traumatic	4	2	3		1		
Decreased embryo viability	2		2				
Deep vein thrombosis postoperative	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Delayed recovery from anaesthesia	4	1	3		1		
Dental leakage	2		1	1	1		
Dental restoration failure	3				3		
Dermal filler overcorrection	1				1		
Dermatitis artefacta	1			1	1		
Device difficult to use	1				1		
Device use confusion	2			1	2		
Device use issue	2			1	2		
Dialysis related complication	2		1	1	1		
Diaphragmatic injury	1		1				
Diffuse axonal injury	2		2				
Dislocation of vertebra	2	1	2				
Diversion colitis	1	1	1				
Documented hypersensitivity to administered product	1				1		
Dose calculation error	4			1	4		
Drug administered in wrong device	1				1		
Drug dose omission by device	1				1		
Drug exposure before pregnancy	21	2	3	11	18	1	1
Drug monitoring procedure incorrectly performed	3				3		
Drug monitoring procedure not performed							1
Drug titration error						1	1
Duodenal rupture	1	1	1				
Duplicate therapy error	3			3	3		
Dysphotopsia	1		1				
Ear canal injury	2	1	2				
Ear injury	19	3	9	2	10		
Electric injury	1	1	1				

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Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Electric shock	49	5	20	11	29		
Endotracheal intubation complication	3	1	3				
Epicondylitis	142	19	50	38	92		
Epidural haemorrhage	3		3				
Epiphyseal injury	1			1	1		
Ergot poisoning	1				1		
Eschar	9	1	3	2	6		
Expired product administered	3649	9	19	2055	3630		1
Exposure during pregnancy	545	22	101	68	444		
Exposure to allergen	2		1	1	1		
Exposure to chemical pollution	1		1				
Exposure to communicable disease	6		1	4	5		
Exposure to contaminated device	1				1		
Exposure to contaminated water	2				2		
Exposure to extreme temperature	2		2				
Exposure to SARS-CoV-2	211	4	33	36	178	3	5
Exposure to toxic agent	4		1		3		
Exposure to unspecified agent	1			1	1		
Exposure to vaccinated person	10		4	3	6		
Exposure via blood	1			1	1		
Exposure via body fluid	1				1		
Exposure via breast milk	5796	46	312	3034	5484	2	3
Exposure via contaminated device	1			1	1		
Exposure via eye contact	24			7	24		
Exposure via father	1		1				
Exposure via partner	1				1		
Exposure via skin contact	114			9	114		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Exposure via unknown route	1				1		
Extra dose administered	540	5	16	34	524		
Extradural haematoma	9	3	9				
Extraskeletal ossification	1			1	1		
Eye contusion	115	12	38	21	77		1
Eye injury	177	12	59	7	118		
Eyelid abrasion	2			1	2		
Eyelid contusion	9		1	4	8		
Eyelid injury	5	1	3	1	2		
Eye luxation	2	1	2				
Face crushing	6	1	6				
Face injury	124	13	81	15	43		4
Facial bones fracture	69	11	69				1
Failed in vitro fertilisation	3	2	3				
Fall	4542	515	2502	563	2040	10	34
Fallopian tube perforation	1		1				
Fascial rupture	1	1	1				
Fat embolism	1		1				
Femoral neck fracture	38	12	38				
Femoral nerve injury	2	2	2				
Femur fracture	48	14	48			1	1
Fibula fracture	7	3	7				
Flail chest	2	1	2				
Foetal exposure during pregnancy	89	18	61	9	28	11	11
Foetal exposure timing unspecified	1	1	1				
Foot fracture	36	7	27	4	9		2
Forearm fracture	1	1	1			1	1

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Foreign body	10	1	2	5	8		
Foreign body aspiration	4		4				
Foreign body in ear	1				1		
Foreign body in eye	17	2	3	5	14		
Foreign body in gastrointestinal tract	2		1	1	1		
Foreign body in mouth	1		1				
Foreign body in respiratory tract	3			2	3		
Foreign body in skin or subcutaneous tissue	2			1	2		
Foreign body in throat	44	5	44				
Foreign body in urogenital tract	1		1				
Fracture	110	40	97	10	13	2	2
Fractured coccyx	2	1	1		1		
Fracture displacement	2	1	2				
Fractured sacrum	3	1	3				
Fractured skull depressed	1		1				
Frostbite	33	5	11	10	22		
Gadolinium deposition disease	1		1				
Gallbladder injury	3		2	1	1		
Gastrointestinal injury	6	1	2	1	4		
Gastrointestinal stoma complication	4		3		1		
Genital injury	2			2	2		
Gingival injury	4	1	1	2	3		
Graft complication							1
Gun shot wound	1		1				
Haemolytic transfusion reaction	1	1	1				
Hair injury	10		1	3	9		
Hand fracture	22	2	20	2	2		

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Injury, poisoning and procedural complications

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Head injury	698	83	441	79	257	2	4
Heat cramps	6		3		3		
Heat exhaustion	43	3	11	3	32		
Heat illness	48	5	30	2	18		
Heat oedema	20		9		11		
Heat stroke	62	3	16	17	46		
Heavy exposure to ultraviolet light	1				1		
Hepatic rupture	1		1				
Hip fracture	50	10	50			2	4
Humerus fracture	20	7	20			1	1
Hyphaema	4	2	4				
Hypobarism	12	2	3	1	9		
Iatrogenic injury	3	1	3				
IIIrd nerve injury	2	2	2				
Iliotibial band syndrome	3		2		1		
Implantation complication	2	1	1	1	1		
Inadequate aseptic technique in use of product	6			1	6		
Inappropriate schedule of product administration	57181	427	960	34619	56221	38	59
Incisional hernia	2		1	1	1		
Incision site complication	3		1	2	2		
Incision site haemorrhage	1		1				
Incision site impaired healing	1		1				
Incision site pain	9		3		6		
Incision site pruritus	1				1		
Incision site rash	2				2		
Incision site swelling	3				3		
Incomplete course of vaccination	124		4	29	120		

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System Organ Class

Injury, poisoning and procedural complications

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Incorrect disposal of product	3			2	3		
Incorrect dosage administered	41			21	41		
Incorrect dose administered	1789	112	124	778	1665	5	5
Incorrect dose administered by device	2				2		
Incorrect dose administered by product	3				3		
Incorrect drug administration rate	2				2		
Incorrect product administration duration	8			2	8		1
Incorrect product dosage form administered	1			1	1		
Incorrect product formulation administered	19			11	19		
Incorrect route of product administration	4908	42	105	1850	4803		1
Induced abortion failed	1		1				
Induced abortion haemorrhage	1		1				
Inflammation of wound	13		3	3	10		
Infusion related reaction	7	1	5		2	5	16
Injection related reaction	79	6	51	3	28		1
Injury	287	32	128	44	159	2	6
Injury corneal	6		3	2	3		1
Injury of conjunctiva	1				1		
Intentional device use issue	1				1		
Intentional dose omission	20		1	1	19	3	3
Intentional overdose	9	2	3	3	6		
Intentional product misuse	18	1	2	3	16		2
Intentional product use issue	17			4	17	2	2
Intentional underdose	2	1	1	1	1	1	1
Intercepted medication error	4				4		
Intercepted product administration error	1				1		
Intercepted product preparation error	2				2		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Intercepted product selection error	1				1		
Intercepted product storage error	1			1	1		
Intervertebral disc injury	3			2	3		
Intoxication by breast feeding	5		5				
Ischaemic contracture of the left ventricle	2	1	2				
IVth nerve injury	1	1	1				
Jaw fracture	21	7	21				
Joint dislocation	99	16	57	17	42		2
Joint injury	171	14	64	23	107	3	6
Kidney contusion	1		1				
Kidney rupture	2	2	2				
Labelled drug-drug interaction medication error	1	1	1				
Lack of vaccination site rotation	3		1		2		1
Laryngeal injury	1		1				
Laryngeal nerve dysfunction	1	1	1				
Lenticular injury	1			1	1		
Ligament injury	13	2	7	2	6		1
Ligament rupture	21	6	13	4	8	1	1
Ligament sprain	135	12	47	26	88		
Limb crushing injury	6	1	6				
Limb injury	517	101	260	60	257	4	7
Lip injury	57	3	19	8	38	1	1
Liver contusion	3		3				
Lower limb fracture	36	8	33	2	3	1	1
Lumbar vertebral fracture	14	3	14			1	3
Lumbosacral plexus injury	2	2	2				
Mallet finger	1				1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Maternal drugs affecting foetus							1
Maternal exposure before pregnancy	355	40	67	141	288	9	11
Maternal exposure during breast feeding	697	29	184	207	513	4	6
Maternal exposure during delivery	1				1		
Maternal exposure during pregnancy	5956	420	1192	1585	4764	58	157
Maternal exposure timing unspecified	1151	76	127	433	1024	5	7
Maternal exposure via partner during pregnancy	1				1		
Mechanical ventilation complication	1		1				
Median nerve injury	5	2	5				
Medical device monitoring error	4			2	4		
Medication error	247	48	57	94	190	1	2
Meniscus injury	22	4	10	5	12	2	2
Metal poisoning	3	1	3				
Mouth injury	39	4	13	5	26		
Mucosal excoriation	1				1		
Multiple fractures	12	1	12				
Multiple injuries	33	10	19	6	14		
Multiple use of single-use product	4			2	4		
Muscle contusion	9		2	1	7		
Muscle hernia	2	1	1		1		
Muscle injury	126	24	65	16	61		
Muscle rupture	80	25	80			2	3
Muscle strain	424	36	143	84	281	1	2
Musculoskeletal injury	4		2	1	2		
Nail avulsion	2			1	2		
Nail injury	5	2	2	3	3		
Nasal injury	22	1	9	1	13		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Near drowning	17	5	17				
Neck crushing	1		1				
Neck injury	25	1	10	1	15		
Needle fatigue	2				2		
Neovaginal pain	1				1		
Nerve injury	473	71	252	67	221		
Nerve root injury	3	1	3				
Nerve root injury lumbar	1		1				
Nerve root injury thoracic	1		1				
Nervous system injury	6	3	6				
Neurological procedural complication	1				1		
Occupational exposure to product	95	1	3	19	92		
Occupational exposure to SARS-CoV-2	14		3		11		
Occupational exposure to sunlight	1		1				
Oesophagitis chemical	1	1	1				
Off label use	54370	10091	16103	19609	38267	200	294
Open fracture	3	3	3				
Optic nerve injury	29	12	29				2
Oral contusion	16		6	4	10		
Oral mucosal scar	5	2	4		1		
Overdose	5144	70	153	1443	4991	4	5
Palate injury	10		1	2	9		
Pancreatic injury	1		1				
Parasympathetic nerve injury	1		1				
Paroxysmal autonomic instability with dystonia	1	1	1				
Patella fracture	9	3	8	1	1		
Paternal exposure before pregnancy	3	1	2	1	1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Paternal exposure during pregnancy	7		1		6		
Paternal exposure timing unspecified	1				1		
Pelvic fracture	25	4	25				1
Penile contusion	2			1	2		
Penis injury	3	1	3				
Periorbital haematoma	24		9	2	15		1
Periorbital haemorrhage	9	2	4	1	5		
Peripancreatic fluid collection	1	1	1				
Peripheral nerve injury	19	5	19				
Periprosthetic fracture	2		2				
Periprosthetic osteolysis	1		1				
Peroneal nerve injury	9	2	6	3	3		
Persistent comeal epithelial defect	1				1		
Petroleum distillate poisoning	1				1		
Pharyngeal contusion	2	1	2				
Phrenic nerve injury	1		1				
Pneumocephalus	2		2				
Pneumoconiosis	3		3				
Pneumonitis chemical	1		1				
Pocket erosion	1			1	1		
Poisoning	41	12	41				
Poor quality device used	1				1		
Poor quality product administered	30828	4	14	17855	30814		
Post concussion syndrome	7	1	1	2	6		
Posterior capsule rupture	1		1				
Posterior tibial nerve injury	3	1	2	1	1		
Post laminectomy syndrome	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Post lumbar puncture syndrome	16	3	6	7	10		
Postmastectomy lymphoedema syndrome	1			1	1		
Postoperative delirium	3	3	3				1
Postoperative ileus	1		1				
Postoperative thrombosis	2		2				
Postoperative wound complication	4		2	1	2		
Post procedural complication	11		8	1	3		3
Post procedural complication circulatory	1			1	1		
Post procedural constipation	1				1		
Post procedural diarrhoea	8			3	8		
Post procedural discomfort	1				1		
Post procedural erythema	1				1		
Post procedural fistula	2		2				
Post procedural haematoma	1	1	1				
Post procedural haematuria	1		1				
Post procedural haemorrhage	13	3	13			2	3
Post procedural hypothyroidism						1	1
Post procedural inflammation	4				4		
Post procedural myocardial infarction	2	2	2				
Post procedural oedema	3		2		1		
Post procedural pruritus	1				1		
Post procedural pulmonary embolism	2	2	2				
Post procedural stroke	1		1				
Post procedural swelling	2	1	1		1		
Post-traumatic neck syndrome	17	2	9	1	8		
Post-traumatic pain	16	1	2	1	14		
Post vaccination syndrome	29	10	17	5	12		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Prescribed overdose	1				1		
Prescribed underdose	2			1	2	1	2
Prescription drug used without a prescription	3		1		2		
Prevertebral soft tissue swelling of cervical space	1			1	1		
Procedural complication	108	3	6	1	102	1	1
Procedural dizziness	15	2	8	1	7		
Procedural haemorrhage	7	1	7				
Procedural headache	3		2		1		
Procedural nausea	14	1	9		5		
Procedural pain	22	4	9	3	13	2	3
Procedural pneumothorax	1	1	1				
Procedural site reaction	2		2				
Procedural vomiting	3		2		1		
Product administered at inappropriate site	1010	39	86	209	924		
Product administered by wrong person	1				1		
Product administered to patient of inappropriate age	8718	9	13	8059	8705		
Product administration error	7586	26	43	6948	7543		
Product administration interrupted	6			5	6		1
Product appearance confusion	3			3	3		
Product communication issue	5			1	5		
Product confusion	8			2	8		
Product design confusion	1			1	1		
Product dispensing error	22			8	22		
Product dispensing issue	1				1		
Product dosage form confusion	1				1		
Product dose omission in error	8			7	8		
Product dose omission issue	142	1	5	5	137	9	14

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Product label confusion	1773			15	1773		
Product name confusion	1			1	1		
Product packaging confusion	10			1	10		
Product preparation error	3153	6	29	1205	3124		
Product preparation issue	2371	4	12	793	2359	1	1
Product prescribing error	14		1	3	13		
Product prescribing issue	1			1	1		
Product selection error	2			2	2		
Product storage error	6966	1	1	5882	6965	1	1
Product substitution error	1				1		
Product use complaint	9		1	2	8		
Product use in unapproved indication	15		2	2	13	1	1
Product use issue	8296	188	576	2544	7720	14	24
Pseudophakic bullous keratopathy	1		1				
Pulmonary contusion	3		3				
Radial nerve injury	14	3	12	1	2		
Radiation associated pain	5	2	2	2	3		
Radiation injury	4	2	2	2	2		
Radiation mastitis	1		1				
Radiation pneumonitis	3	1	1		2		
Radiation proctitis	1		1				
Radiation sickness syndrome	2			1	2		
Radiation skin injury	1	1	1				
Radius fracture	11	5	7	1	4		
Reaction to previous exposure to any vaccine	3	2	3				
Reactive gastropathy	6	1	2	4	4		
Recalled product administered	3				3		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Recall phenomenon	12	2	4	1	8		
Rectal injury	1		1				
Refractoriness to platelet transfusion	1				1		
Renal transplant failure	4	2	4				
Re-opening of ductus arteriosus	1				1		
Repetitive strain injury	3	1	3				
Reproductive tract anastomotic leak	1			1	1		
Respiratory fume inhalation disorder	1		1				
Retinal injury	17	5	17				
Rib fracture	99	18	86	6	13		1
Road traffic accident	171	50	122	13	49	3	6
Scapula fracture	3		3				
Scar	243	30	76	53	167	3	3
Sciatic nerve injury	12	2	8		4		
Scratch	212	7	47	35	165	1	2
Scrotal injury	1				1		
Seroma	10	2	4	2	6		
Shunt blood flow excessive	1		1				
Shunt occlusion	3		3				
Shunt stenosis	1				1		
Shunt thrombosis	3	1	3				
Silicosis	1		1				
Skeletal injury	13	2	6		7		
Skin abrasion	151	10	44	39	107		
Skin flap necrosis						1	1
Skin injury	60	5	17	12	43		
Skin laceration	169	15	82	30	87		1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skin pressure mark	1				1		
Skin procedural complication	1	1	1				
Skin scar contracture	1				1		
Skin wound	37	4	12	11	25		
Skull fracture	18	3	18				
Skull fractured base	11	1	11				
Snake bite	3		1	1	2		
Soft tissue foreign body	6				6		
Soft tissue injury	10	3	8	1	2		
Spinal column injury	12	2	7	1	5		
Spinal compression fracture	23	8	23				
Spinal cord injury	25	10	25				
Spinal cord injury cauda equina	1		1				
Spinal cord injury cervical	4	4	4				
Spinal cord injury thoracic	2	1	2				
Spinal fracture	41	12	41			3	5
Spinal shock	1		1				
Splenic injury	2		1	1	1		
Splenic rupture	18	4	18				
Splinter	3				3		
Sports injury	1				1		
Stab wound	4	1	1	1	3		
Sternal fracture	6	2	6				
Sternal injury	1			1	1		
Stoma complication	1		1				
Stoma obstruction	1	1	1				
Stoma site discharge	2		2				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Stoma site erythema	1				1		
Stoma site extravasation	1				1		
Stoma site haemorrhage	6	1	6				
Stoma site inflammation	1				1		
Stoma site pain	2		1		1		
Stoma site pruritus	2				2		
Stoma site vasculitis	1	1	1				
Stress fracture	8	1	6	1	2		
Subarachnoid haematoma	3	1	3				
Subcutaneous haematoma	89	4	29	10	60		
Subdural haematoma	146	36	146			1	1
Subdural haemorrhage	36	6	36				
Sunburn	110	3	22	6	88	1	1
Superficial injury of eye	8		1	2	7		
Suture related complication	3		1	1	2		
Suture rupture	1			1	1		
Sympathetic nerve injury	1	1	1				
Synovial rupture	11		6	3	5		
Tendon injury	33	2	19	3	14		
Tendon rupture	90	22	59	16	31		1
Testicular injury	2		1	1	1		
Thermal burn	133	10	39	33	94		
Thermal burns of eye	35	8	35				
Thoracic vertebral fracture	14	9	14			1	1
Tibia fracture	12	3	9	3	3	1	1
Tissue injury	11	2	6	2	5		
Tongue injury	20	1	8	4	12		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tooth avulsion	4		4				
Tooth dislocation	2			1	2		
Tooth fracture	58	3	32	5	26		
Tooth injury	50	5	27	9	23		
Torus fracture	2		1		1		
Toxic anterior segment syndrome	1		1				
Toxicity to various agents	42	9	34	3	8		1
Tracheal deviation	2		2				
Tracheal haemorrhage	1		1				
Tracheal obstruction	9	2	9				
Tracheostomy malfunction	2	1	2				
Transcription medication error	1				1		
Transfusion reaction	3	1	1		2		
Transfusion related complication	1		1				
Transplantation complication	1	1	1				
Transplant dysfunction	2	1	2				
Transplant failure	2		2				
Traumatic fracture	2	1	2				
Traumatic haematoma	22	2	11	3	11		
Traumatic haemorrhage	8	1	5		3		
Traumatic haemothorax	5	3	5				
Traumatic heart injury	2	1	2				
Traumatic intracranial haemorrhage	13	4	13				
Traumatic liver injury	2	1	2				
Traumatic lung injury	13	2	9	1	4		
Traumatic shock	1			1	1		
Trunk injury	3			1	3		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Twiddler's syndrome	1			1	1		
Ulna fracture	5	2	4		1		
Ulnar nerve injury	22	3	11	4	11		
Underdose	2854	6	12	1050	2842		
Upper limb fracture	67	15	62	1	5		1
Urethral injury	1		1				
Uterine injury	1		1				
Uterine rupture	1	1	1			1	1
Uveal prolapse	1	1	1				
Vaccination complication	80	6	20	20	60	8	14
Vaccination error	943	6	12	800	931		
Vascular access complication	1	1	1				
Vascular access malfunction	2		1		1		
Vascular access site dissection	1	1	1				
Vascular access site swelling	1				1		
Vascular graft occlusion	4	3	4				
Vascular graft stenosis	1		1				
Vascular graft thrombosis	7		7				
Vascular injury	57	9	24	13	33		
Vascular procedure complication	1		1				
Vascular pseudoaneurysm	6	1	5		1		
Vasoplegia syndrome	7	1	7				
Vena cava injury	1		1				
Venous injury	12	1	12				
VIIIth nerve injury	9	4	8		1		
VIIth nerve injury	8	2	7		1		
Vitreous injury	2	1	2				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vth nerve injury	2		2				
Vulvovaginal injury	11	2	11				
Weaning failure	2	1	1	1	1		
Wound	288	25	98	71	190	3	5
Wound complication	57	3	14	18	43		1
Wound contamination	1		1				
Wound dehiscence	3	1	2		1		
Wound haematoma	2	1	1		1		
Wound haemorrhage	68	8	28	10	40		2
Wound necrosis	5	1	5				
Wound secretion	31	3	17	9	14		2
Wrist fracture	21	4	20	1	1	1	1
Wrong dosage formulation	1				1		
Wrong dose	14			5	14		
Wrong drug	3				3		
Wrong patient	1				1		
Wrong patient received product	3			1	3		
Wrong product administered	776	2	15	160	761		
Wrong product stored	1				1		
Wrong schedule	19	2	2	9	17		
Wrong strength	1			1	1		
Wrong technique in device usage process	5				5		
Wrong technique in product usage process	972	15	38	138	934		
Total:	241342	14184	30116	115251	211226	464	839

System Organ Class

Investigations

Spontaneous		Non Interventional Study	

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
5-hydroxyindolacetic acid in urine	1			1	1		
Acid base balance	1			1	1		
Acid base balance abnormal	3		2	1	1		
Acoustic stimulation tests	1		1				
Acoustic stimulation tests abnormal	2		1		1		
Acoustic stimulation tests normal	1				1		
Activated partial thromboplastin time abnormal	4		1	2	3		
Activated partial thromboplastin time prolonged	88	9	46	5	42		
Activated partial thromboplastin time ratio decreased	7			3	7		
Activated partial thromboplastin time ratio increased	4		1	1	3		
Activated partial thromboplastin time shortened	39	1	14	4	25		
ADAMTS13 activity abnormal	2		2				
ADAMTS13 activity decreased	5	2	4		1		
Adenosine deaminase increased	3		1		2		
Adenovirus test positive	2				2		
Adjusted calcium decreased	2		1		1		
Airway peak pressure increased	2	1	1		1		
Alanine aminotransferase abnormal	18	2	8	5	10		
Alanine aminotransferase decreased	13	1	2	3	11		
Alanine aminotransferase increased	482	54	208	68	274	1	3
Albumin CSF abnormal	3	2	3				
Albumin CSF increased	5	1	5				
Albumin globulin ratio abnormal	1		1				
Albumin globulin ratio decreased	15		2	3	13		
Albumin globulin ratio increased	4				4		
Albumin urine	1			1	1		
Albumin urine absent	1		1				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Albumin urine present	8		3	3	5		
Alcohol test false positive	1				1		
Aldolase increased	7	2	4	1	3		
Aldosterone urine increased	1			1	1		
Allergy alert test	1				1		
Allergy test	1	1	1				
Allergy test negative	4			3	4		
Allergy test positive	6	1	1	3	5		
Alpha-1 acid glycoprotein increased	1			1	1		
Alpha-1 anti-trypsin increased	2		1	1	1		
Alpha 1 foetoprotein abnormal	1			1	1		
Alpha 1 foetoprotein decreased	1		1				
Alpha 1 foetoprotein increased	2			1	2		
Alpha 1 globulin decreased	2		1		1		
Alpha 1 globulin increased	6		1	1	5		
Alpha 2 globulin decreased	3		2	1	1		
Alpha 2 globulin increased	7			3	7		
Alpha-2 macroglobulin increased	1			1	1		
Alpha globulin increased	4				4		
Alpha tumour necrosis factor increased	2		1		1		
Amino acid level decreased	1				1		
Amino acid level increased	3			1	3		
Ammonia abnormal	1				1		
Ammonia increased	4	1	2	1	2		1
Amniocentesis abnormal	4	3	4				
Amniotic fluid volume decreased	8	1	8				
Amniotic fluid volume increased	2	1	2				

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Amniotic membrane rupture test positive	1	1	1				
Amphetamines	1			1	1		
Amphetamines positive	3				3		
Amylase abnormal	2			1	2		
Amylase decreased	12		4	1	8		
Amylase increased	60	3	28	9	32		
Analgesic drug level	4		3	1	1		
Analgesic drug level above therapeutic	1		1				
Analgesic drug level increased	1				1		
Anal pap smear abnormal	1			1	1		
Androgens increased	2	1	1		1		
Angiocardiogram	2	1	1	1	1		
Angiogram	3			1	3		
Angiogram abnormal	3	1	1		2		
Angiogram cerebral abnormal	1	1	1				
Angiogram pulmonary abnormal	4		2	1	2		
Angiotensin converting enzyme decreased	6		1	4	5		
Angiotensin converting enzyme increased	10	1	5	2	5		
Angiotensin II abnormal	1			1	1		
Angiotensin II decreased	1			1	1		
Angiotensin II receptor type 1 antibody positive	1				1		
Anion gap abnormal	1				1		
Anion gap decreased	5			2	5		1
Anion gap increased	12	1	2		10		
Antiacetylcholine receptor antibody positive	3		1	1	2		
Anti-actin antibody positive	1			1	1		
Anti-aquaporin-4 antibody positive	3		3				

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anti B antibody positive	1				1		
Antibody test	1			1	1		
Antibody test abnormal	115	3	9	50	106		
Antibody test negative	25		2	12	23		
Antibody test normal	1				1		
Antibody test positive	17	3	6	6	11		
Anticoagulation drug level	1			1	1		
Anticoagulation drug level above therapeutic	3				3		
Anticoagulation drug level below therapeutic	9		2		7		
Anticoagulation drug level increased	1		1				
Anticonvulsant drug level below therapeutic	2	1	1	1	1		
Anticonvulsant drug level decreased	2	2	2				
Anti-cyclic citrullinated peptide antibody positive	17	2	5	7	12		
Antidepressant drug level decreased	2			2	2		
Antidepressant drug level increased	1			1	1		
Anti-erythrocyte antibody positive	2	1	1	1	1		
Anti factor IX antibody increased	1		1				
Anti factor V antibody positive	1	1	1				
Anti factor VIII antibody increased	1		1				
Anti factor VIII antibody positive	3		3				
Anti-GAD antibody positive	8	1	2	2	6		
Anti-ganglioside antibody negative	1			1	1		
Anti-ganglioside antibody positive	5		1	3	4		
Anti-glomerular basement membrane antibody positive	1		1				
Anti-HLA antibody test positive	1			1	1		
Anti-IA2 antibody positive	4		1		3		
Anti-insulin antibody increased	1			1	1		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anti-insulin antibody positive	1				1		
Anti-islet cell antibody positive	3		2		1		
Anti Kell antibody test positive	1				1		
Anti-melanoma differentiation-associated protein 5 antibody	3	2	3				
Antimicrobial susceptibility test resistant	1	1	1				
Antimitochondrial antibody positive	3			1	3		
Anti-Muellerian hormone level decreased	9	3	4	4	5		
Anti-myelin-associated glycoprotein antibodies positive	3		3				
Anti-neuronal antibody	2		1		1		
Anti-neuronal antibody positive	1			1	1		
Antineutrophil cytoplasmic antibody	1		1				
Antineutrophil cytoplasmic antibody decreased	1				1		
Antineutrophil cytoplasmic antibody increased	16	7	10	5	6		
Antineutrophil cytoplasmic antibody positive	21	6	13	4	8		
Antinuclear antibody	13	3	5	6	8		
Antinuclear antibody increased	50	8	16	17	34		
Antinuclear antibody negative	1			1	1		
Antinuclear antibody positive	131	17	39	39	92		
Antiphospholipid antibodies	6	1	3	2	3		
Antiphospholipid antibodies positive	26	4	14	6	12		
Anti-platelet antibody	1		1				
Anti-platelet antibody positive	5	1	4	1	1		
Anti-platelet factor 4 antibody negative	1			1	1		
Anti-platelet factor 4 antibody positive	3	1	1	1	2		
Anti-polyethylene glycol antibody present	1		1				
Anti-prothrombin antibody positive	1				1		
Antipsychotic drug level below therapeutic	1				1		

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Antipsychotic drug level increased	4		2		2		
Anti-saccharomyces cerevisiae antibody test positive	1			1	1		
Anti-SRP antibody positive	2	2	2				
Antithrombin III decreased	3		1	1	2		
Antithrombin III increased	1		1				
Anti-thyroid antibody	10		2	4	8		
Anti-thyroid antibody decreased	1				1		
Anti-thyroid antibody increased	41	10	14	24	27		
Anti-thyroid antibody positive	32	2	9	7	23		
Anti-zinc transporter 8 antibody positive	2			1	2		
Antral follicle count low	2			2	2		
Aortic bruit	5	1	2	1	3		
Apgar score abnormal	1	1	1				
Apgar score low	2		2				
Apnoea test abnormal	1			1	1		
Apolipoprotein B increased	1			1	1		
Arteriogram abnormal	1		1				
Arteriogram coronary normal	1		1				
Aspartate aminotransferase	1		1				
Aspartate aminotransferase abnormal	14	1	7	2	7		
Aspartate aminotransferase decreased	3				3		
Aspartate aminotransferase increased	395	39	144	69	251		1
Aspergillus test positive	3	1	2		1		
Aspiration bone marrow	1	1	1				
Aspiration joint	3			1	3		
AST/ALT ratio abnormal	4	1	2		2		
Asymmetric di-methylarginine increased	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Atrial pressure increased	3	1	1		2		
Audiogram abnormal	6		2	1	4		
Auscultation	1				1		
Autoantibody negative	1		1				
Autoantibody positive	64	9	16	31	48		
Autoantibody test	3	1	1	2	2		
Bacillus test positive	2		1		1		
Bacterial test	3		2		1		
Bacterial test negative	1			1	1		
Bacterial test positive	41	2	21	5	20		1
Balance test	1	1	1				
Band neutrophil count decreased	1				1		
Band neutrophil count increased	2		1		1		1
Band neutrophil percentage increased	3		1		2		1
Bartonella test positive	2			1	2		
Base excess abnormal	1		1				
Base excess decreased	5		2	2	3		
Base excess increased	3			1	3		
Basophil count abnormal	3			1	3		
Basophil count decreased	6		1	1	5		
Basophil count increased	27	1	4	6	23		
Basophil percentage decreased	1				1		
Basophil percentage increased	2			1	2		
Bence Jones protein urine present	1			1	1		
Beta-2 glycoprotein antibody positive	7	1	3	1	4		
Beta 2 microglobulin abnormal	1				1		
Beta 2 microglobulin increased	10	2	6	2	4		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Beta 2 microglobulin urine increased	1		1				
Beta globulin	1				1		
Beta globulin abnormal	1				1		
Beta globulin decreased	2				2		
Beta globulin increased	5		1		4		
Bile output	1				1		
Bile output abnormal	3			3	3		
Bile output increased	2		1		1		
Bilirubin conjugated	2	1	1	1	1		
Bilirubin conjugated increased	17	3	7		10		
Bilirubin urine present	4		1		3		
Biopsy	2	1	1	1	1		
Biopsy bone	1	1	1				
Biopsy bone marrow abnormal	2		2				
Biopsy breast	2	1	2				
Biopsy breast abnormal	2		1		1		
Biopsy endometrium	1		1				
Biopsy heart	1			1	1		
Biopsy heart abnormal	1	1	1				
Biopsy intestine abnormal	1	1	1				
Biopsy kidney abnormal	1		1				
Biopsy lymph gland	4	1	1	1	3		
Biopsy lymph gland normal	1	1	1				
Biopsy muscle abnormal	1		1				
Biopsy peripheral nerve	1		1				
Biopsy skin abnormal	1		1				
Blast cell count increased	2		2				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blast cells	1	1	1				
Blast cells present	1				1		
Bleeding time	1		1				
Bleeding time abnormal	3	1	2		1		
Bleeding time prolonged	49	6	18	12	31		1
Bleeding time shortened	2		1		1		
Blood 1,25-dihydroxycholecalciferol increased	1	1	1				
Blood 25-hydroxycholecalciferol decreased	5			3	5		
Blood acid phosphatase increased	1				1		
Blood albumin	1				1		
Blood albumin abnormal	5		3		2		
Blood albumin decreased	98	3	28	19	70		
Blood albumin increased	16	1	5	4	11		
Blood alcohol abnormal	1				1		
Blood alcohol decreased	2		1		1		
Blood alcohol increased	4		3		1		
Blood aldosterone increased	2				2		
Blood alkaline phosphatase	2	2	2				
Blood alkaline phosphatase abnormal	2		1	1	1		
Blood alkaline phosphatase decreased	16		2	4	14		
Blood alkaline phosphatase increased	141	10	47	23	94		
Blood aluminium increased	1				1		
Blood androstenedione increased	1			1	1		
Blood antidiuretic hormone abnormal	1	1	1				
Blood antidiuretic hormone increased	1		1				
Blood beta-D-glucan positive	1			1	1		
Blood bicarbonate decreased	25	1	9	7	16		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood bicarbonate increased	6		1	1	5		
Blood bilirubin abnormal	10	2	3	3	7		
Blood bilirubin decreased	12			3	12		
Blood bilirubin increased	176	17	62	27	114		
Blood bilirubin unconjugated increased	6	2	3	1	3		
Blood caffeine decreased	1		1				
Blood calcium abnormal	6	1	2	2	4		
Blood calcium decreased	53	3	12	8	41		
Blood calcium increased	25		5	9	20	1	1
Blood catecholamines increased	2				2		
Blood chloride decreased	28		1	4	27		
Blood chloride increased	33		4	5	29		
Blood cholesterol	4	2	3		1	1	1
Blood cholesterol abnormal	13			2	13		
Blood cholesterol decreased	17		3	3	14		
Blood cholesterol increased	263	25	62	57	201		1
Blood cholinesterase decreased	10		3		7		
Blood cholinesterase increased	7		4		3		
Blood chromium decreased	1				1		
Blood chromium increased	2		2				
Blood chromogranin A increased	1				1		
Blood copper	1		1				
Blood copper increased	3				3		
Blood corticotrophin	1		1				
Blood corticotrophin decreased	1	1	1				
Blood creatine abnormal	1				1		
Blood creatine decreased	7	1	3		4		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood creatine increased	48	4	15	9	33		
Blood creatine phosphokinase	4	1	2	2	2		
Blood creatine phosphokinase abnormal	12	2	4	2	8		
Blood creatine phosphokinase decreased	31	3	8	4	23		
Blood creatine phosphokinase increased	632	84	341	122	291		1
Blood creatine phosphokinase MB	3	1	1	2	2		
Blood creatine phosphokinase MB abnormal	1			1	1		
Blood creatine phosphokinase MB decreased	1			1	1		
Blood creatine phosphokinase MB increased	115	22	66	11	49	1	1
Blood creatine phosphokinase MM increased	2	1	1	1	1		
Blood creatine phosphokinase normal	1				1		
Blood creatinine abnormal	16	1	7	3	9		
Blood creatinine decreased	49	3	9	8	40		
Blood creatinine increased	310	30	119	43	191	1	3
Blood culture positive	3		1	1	2		
Blood electrolytes decreased	9	2	7	2	2		
Blood electrolytes increased	1				1		
Blood erythropoietin decreased	1			1	1		
Blood fibrinogen abnormal	7	1	3	1	4		
Blood fibrinogen decreased	23	1	9	7	14		
Blood fibrinogen increased	145	13	48	22	97		
Blood folate decreased	36	8	16	2	20		
Blood folate increased	5	1	1		4		
Blood follicle stimulating hormone abnormal	2			2	2		
Blood follicle stimulating hormone increased	27	3	10	9	17		
Blood gases abnormal	8	2	7	1	1		
Blood gases normal	1		1				

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood glucagon abnormal	2			1	2		
Blood glucagon decreased	1				1		
Blood glucagon increased	3		1		2		
Blood glucose	4		2		2		
Blood glucose abnormal	157	8	42	48	115	2	4
Blood glucose decreased	356	14	120	50	236		1
Blood glucose fluctuation	150	11	49	29	101		
Blood glucose increased	1296	88	405	222	891	1	4
Blood glucose normal	4				4		
Blood gonadotrophin increased	1				1		
Blood growth hormone	1				1		
Blood growth hormone abnormal	2				2		
Blood growth hormone decreased	3			2	3		
Blood growth hormone normal	2			2	2		
Blood HIV RNA increased	1	1	1				
Blood homocysteine decreased	1				1		
Blood homocysteine increased	15	4	8	4	7		
Blood immunoglobulin A	1				1		
Blood immunoglobulin A abnormal	1				1		
Blood immunoglobulin A decreased	4		1		3		
Blood immunoglobulin A increased	22	1	4	6	18		
Blood immunoglobulin E	2				2		
Blood immunoglobulin E abnormal	1			1	1		
Blood immunoglobulin E decreased	1				1		
Blood immunoglobulin E increased	80	10	27	13	53		
Blood immunoglobulin G	2	1	1		1		
Blood immunoglobulin G abnormal	2			1	2		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood immunoglobulin G decreased	23	3	4	6	19		
Blood immunoglobulin G increased	47	6	13	12	34		
Blood immunoglobulin M abnormal	1		1				
Blood immunoglobulin M decreased	14	1	3	5	11		
Blood immunoglobulin M increased	18	3	3	2	15		
Blood insulin	2				2		
Blood insulin abnormal	3	2	2		1		
Blood insulin decreased	2	1	1		1		
Blood insulin increased	4	2	2	1	2		
Blood iron	2		1		1		
Blood iron abnormal	8	3	3	2	5		
Blood iron decreased	165	20	63	46	102	4	5
Blood iron increased	32	3	6	11	26		
Blood ketone body	4		1	1	3		
Blood ketone body increased	10	2	6	3	4		
Blood ketone body present	2		1		1		
Blood lactate dehydrogenase abnormal	7	1	2	2	5		
Blood lactate dehydrogenase decreased	9	1	3	2	6		
Blood lactate dehydrogenase increased	274	23	107	45	167		
Blood lactic acid	13	2	3	3	10		
Blood lactic acid abnormal	4				4		
Blood lactic acid decreased	4		2		2		
Blood lactic acid increased	74	7	38	9	36		
Blood lead	1				1		
Blood luteinising hormone abnormal	6			3	6		
Blood luteinising hormone decreased	6	1	2	1	4		
Blood luteinising hormone increased	8	1	3	2	5		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood magnesium abnormal	1				1		
Blood magnesium decreased	27	3	10	6	17	1	1
Blood magnesium increased	3		1		2		
Blood methaemoglobin present	2				2		
Blood oestrogen	2			2	2		
Blood oestrogen abnormal	7		3	2	4		
Blood oestrogen decreased	19		2	3	17		
Blood oestrogen increased	24	1	6	9	18		
Blood osmolarity decreased	7	4	6		1		
Blood osmolarity increased	3			1	3		
Blood parathyroid hormone abnormal	2	1	1	1	1		
Blood parathyroid hormone decreased	2			1	2		
Blood parathyroid hormone increased	11			3	11		
Blood pH	2		2				
Blood pH abnormal	6		6				
Blood pH decreased	7		4	2	3		
Blood pH increased	21	2	13	2	8		
Blood phosphorus	1		1				
Blood phosphorus abnormal	1				1		
Blood phosphorus decreased	25	1	8	5	17	1	1
Blood phosphorus increased	14		3	4	11		
Blood potassium abnormal	12		4	5	8		
Blood potassium decreased	195	18	83	22	112	1	1
Blood potassium increased	75	5	25	8	50	1	2
Blood pressure abnormal	767	87	248	190	519	1	1
Blood pressure ambulatory abnormal	5		2	2	3		
Blood pressure ambulatory decreased	1	1	1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood pressure ambulatory increased	17		5	2	12		
Blood pressure decreased	3695	241	1633	578	2062	2	9
Blood pressure diastolic	2				2		
Blood pressure diastolic abnormal	2		1	1	1	2	2
Blood pressure diastolic decreased	148	5	65	13	83	1	1
Blood pressure diastolic increased	161	6	51	25	110	3	4
Blood pressure difference of extremities	2		1		1		
Blood pressure immeasurable	46	3	36	2	10		
Blood pressure increased	14161	1079	5180	3381	8981	21	52
Blood pressure measurement	63	7	18	26	45		
Blood pressure normal	5		1	1	4		
Blood pressure orthostatic	1	1	1				
Blood pressure orthostatic abnormal	4		2		2		
Blood pressure orthostatic decreased	6		3	1	3		
Blood pressure orthostatic increased	1				1		
Blood pressure systolic	7		4	1	3		
Blood pressure systolic abnormal	6	1	2		4	1	1
Blood pressure systolic decreased	108	9	60	10	48		
Blood pressure systolic increased	550	30	262	56	288	4	7
Blood pressure systolic inspiratory decreased	1				1		
Blood prolactin	3		1		2		
Blood prolactin increased	26	2	4	13	22		
Blood pyruvic acid increased	1		1				
Blood smear test abnormal	3			1	3		
Blood sodium abnormal	7	2	4	2	3		
Blood sodium decreased	128	10	56	8	72	1	3
Blood sodium increased	18	2	7		11		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood test	10	1	7	2	3		
Blood test abnormal	231	29	104	45	127	1	3
Blood test normal	2		1		1		
Blood testosterone abnormal	1				1		
Blood testosterone decreased	16	2	5	3	11		
Blood testosterone free decreased	1				1		
Blood testosterone increased	8	1	3	1	5		
Blood thrombin increased	2				2		
Blood thromboplastin increased	1				1		
Blood thyroid stimulating hormone	2				2		
Blood thyroid stimulating hormone abnormal	23	1	2	16	21		
Blood thyroid stimulating hormone decreased	112	7	34	40	78		
Blood thyroid stimulating hormone increased	258	22	61	80	197		
Blood thyroid stimulating hormone normal	1				1		
Blood triglycerides abnormal	8			3	8		
Blood triglycerides decreased	4	1	1		3		
Blood triglycerides increased	86	5	17	15	69		1
Blood urea	1			1	1		
Blood urea abnormal	8		1	2	7		
Blood urea decreased	22	2	8	2	14		
Blood urea increased	146	2	37	20	109		
Blood urea nitrogen/creatinine ratio decreased	1				1		
Blood urea nitrogen/creatinine ratio increased	4		1	1	3		
Blood uric acid	1				1		
Blood uric acid abnormal	6	1	1	2	5		
Blood uric acid decreased	10		1	4	9		
Blood uric acid increased	75	13	25	13	50		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood urine	75	8	33	17	42		
Blood urine present	499	48	172	125	327	2	3
Blood viscosity abnormal	4				4		
Blood viscosity decreased	2		1		1		
Blood viscosity increased	15	2	4	5	11		
Blood zinc abnormal	1			1	1		
Blood zinc decreased	8			2	8		
B-lymphocyte count abnormal	2			2	2		
B-lymphocyte count decreased	8	2	3	2	5		
B-lymphocyte count increased	2			1	2		
Body height abnormal	1				1		
Body height decreased	58		3	4	55		
Body mass index	1	1	1				
Body mass index abnormal	2			1	2		
Body mass index increased	9			2	9		
Body temperature	260	14	68	37	192		
Body temperature abnormal	738	63	211	303	527	1	2
Body temperature decreased	686	30	159	158	527	3	5
Body temperature fluctuation	379	25	120	78	259		
Body temperature increased	13528	178	849	3499	12679	4	17
Body temperature normal	6			5	6		
Bone density abnormal	2			1	2		
Bone density decreased	5		2	1	3		
Bone density increased	1		1				
Bone marrow myelogram abnormal	2		2				
Borrelia test positive	17	3	5	8	12		
Brachial pulse decreased	4	2	2		2	2	2

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Brachial pulse increased	3	1	1	1	2		
Brain natriuretic peptide	1		1				
Brain natriuretic peptide abnormal	6	1	4		2		
Brain natriuretic peptide decreased	1		1				
Brain natriuretic peptide increased	139	16	71	21	68		
Brain scan abnormal	6		3	1	3		
Brain scan normal	1			1	1		
Breast scan	1		1				
Breast scan abnormal	1				1		
Breath sounds	27	2	4	10	23		
Breath sounds abnormal	127	10	70	14	57	2	3
Brucella test positive	1	1	1				
Calcium ionised decreased	4		3		1		
Calcium ionised increased	3	1	1	1	2		
Campylobacter test positive	4		1	2	3		
Capillary fragility increased	6		2	1	4		
Capillary nail refill test	1				1		
Capillary nail refill test abnormal	16	2	7	2	9		
Capillary permeability	1			1	1		
Capillary permeability increased	5	2	5			1	1
Carbohydrate antigen 125 increased	13	3	3	2	10		
Carbohydrate antigen 15-3 increased	8	2	2	1	6		
Carbohydrate antigen 19-9 increased	4		2		2		
Carbon dioxide abnormal	1			1	1		
Carbon dioxide decreased	12		1	3	11		
Carbon dioxide increased	11	1	5	3	6		
Carboxyhaemoglobin decreased	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Carboxyhaemoglobin increased	3		1	1	2		
Carcinoembryonic antigen increased	19	7	19				
Cardiac clearance	1			1	1		
Cardiac function test abnormal	7	2	3	2	4		
Cardiac imaging procedure abnormal	3	1	2		1		
Cardiac index increased	1		1				
Cardiac murmur	160	22	76	33	84	4	5
Cardiac murmur functional	2	1	1		1		
Cardiac output	2	1	1		1		
Cardiac output decreased	12	3	10	1	2		
Cardiac stress test abnormal	7	1	3	1	4		
Cardiac stress test normal	1			1	1		
Cardio-ankle vascular index	1				1		
Cardiolipin antibody	2		1	1	1		
Cardiolipin antibody positive	12		2	4	10		
Cardiopulmonary exercise test abnormal	2	1	1		1		
Cardiothoracic ratio increased	8		2	1	6		
Cardiovascular function test abnormal	1		1				
Carotid bruit	4		3	1	1		
Carotid intima-media thickness increased	2	1	2				
Carotid pulse	4		1		3		
Carotid pulse abnormal	3			1	3		
Carotid pulse decreased	1				1		
Carotid pulse increased	1			1	1		
Catecholamines urine increased	1				1		
Catheterisation cardiac	8	2	4	4	4		
Catheterisation cardiac abnormal	1				1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
CD19 lymphocytes decreased	2			1	2		
CD19 lymphocytes increased	1				1		
CD4/CD8 ratio decreased	1			1	1		
CD4/CD8 ratio increased	5			2	5		
CD4 lymphocyte percentage increased	1			1	1		
CD4 lymphocytes decreased	9		4	1	5		
CD4 lymphocytes increased	2			2	2		
CD8 lymphocyte percentage decreased	1				1		
CD8 lymphocytes decreased	3			1	3		
CD8 lymphocytes increased	2	1	1		1		
Cell marker decreased	1		1				
Cell marker increased	1				1		
Cells in urine	2		2				1
Central venous pressure abnormal	2	1	1		1		
Ceruloplasmin decreased	2			1	2		
Ceruloplasmin increased	1			1	1		
Chemokine increased	2	1	1		1		
Chest expansion decreased	3			1	3		
Chest scan	1				1		
Chest X-ray	7		2	5	5		
Chest X-ray abnormal	42	4	21	8	21		
Chest X-ray normal	4		1	2	3		
Chlamydia test positive	5			3	5		
Chromosome analysis abnormal	1	1	1				
Circulating anticoagulant positive	2	1	2				
Clostridium test positive	5	1	5				
Clot retraction	3		2		1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Clot retraction abnormal	1				1		
Coagulation factor decreased	1				1		
Coagulation factor increased	8	1	5	2	3		
Coagulation factor VIII level abnormal	1	1	1				
Coagulation factor VIII level decreased	4		2	1	2		
Coagulation factor VIII level increased	8	1	5	1	3		
Coagulation factor VII level decreased	1	1	1				
Coagulation factor VII level increased	1			1	1		
Coagulation factor V level abnormal	2	1	1		1		
Coagulation factor V level decreased	1		1				
Coagulation factor XIII level decreased	2	1	1	1	1		
Coagulation test abnormal	19	3	8	6	11		
Coagulation time	1				1		
Coagulation time abnormal	2		1	1	1		
Coagulation time prolonged	26	1	9	4	17		
Coagulation time shortened	9		3	3	6		
Cold agglutinins	2			1	2		
Cold agglutinins positive	1			1	1		
Colonoscopy	3			3	3		
Colonoscopy abnormal	2			2	2		
Colonoscopy normal	1				1		
Coma scale	2	2	2				
Coma scale abnormal	58	7	53	3	5		
Coma scale normal	1		1				
Complement factor abnormal	1			1	1		
Complement factor C1 increased	1				1		
Complement factor C3 decreased	7	1	3		4		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Complement factor C3 increased	7		1		6		
Complement factor C4 decreased	4		1		3		
Complement factor C4 increased	1				1		
Complement factor decreased	5	1	4		1		
Complement factor increased	5		2	1	3		
Computerised tomogram	1		1				
Computerised tomogram abdomen	1				1		
Computerised tomogram abdomen abnormal	2	1	2				
Computerised tomogram abnormal	18	2	7	5	11		
Computerised tomogram head	2	1	2				
Computerised tomogram head abnormal	4	1	1		3		
Computerised tomogram liver abnormal	1			1	1		
Computerised tomogram normal	1				1		
Computerised tomogram pancreas abnormal	2	1	2				
Computerised tomogram thorax	3			3	3		
Computerised tomogram thorax abnormal	6	2	3	2	3		
Conjunctival staining	2				2		
Coombs direct test positive	3	2	3				
Coombs test positive	3		1	1	2		
Corneal reflex decreased	24	1	15	2	9		
Coronavirus test	3	1	3				
Coronavirus test negative	1			1	1		
Coronavirus test positive	11	2	7	1	4	2	2
Cortisol abnormal	6	1	1	2	5		
Cortisol decreased	18	2	9	4	9		
Cortisol free urine increased	1		1				
Cortisol increased	17	2	3	5	14		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Coxiella test positive	2	1	2				
Coxsackie virus test positive	4		2	1	2		
C-reactive protein	11	1	2	6	9		
C-reactive protein abnormal	55	4	23	19	32		
C-reactive protein decreased	24	3	7	5	17		
C-reactive protein increased	2409	249	1057	430	1352	2	5
Creatine urine decreased	1		1				
Creatine urine increased	2			1	2		
Creatinine renal clearance abnormal	2		1		1		
Creatinine renal clearance decreased	8	1	5	2	3		
Creatinine renal clearance increased	2		1	1	1		
Creatinine urine decreased	2		1	1	1		
Creatinine urine increased	2		1		1		
Cryoglobulins present	1				1		
Crystal urine	2		1		1		
Crystal urine present	1				1		
CSF cell count abnormal	3		3				
CSF cell count decreased	1				1		
CSF cell count increased	26	9	26				
CSF culture positive	2	2	2				
CSF glucose decreased	3	2	3				
CSF glucose increased	11	2	11				
CSF immunoglobulin increased	7	1	7				
CSF lactate increased	2	1	2				
CSF lymphocyte count abnormal	1		1				
CSF lymphocyte count increased	6		6				
CSF mononuclear cell count decreased	1				1		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
CSF mononuclear cell count increased	1		1				
CSF myelin basic protein increased	4		4				
CSF neutrophil count positive	1		1				
CSF oligoclonal band	4	3	4				
CSF oligoclonal band present	20	8	20				
CSF polymorphonuclear cell count increased	2		2				
CSF pressure	2		1	1	1	1	1
CSF pressure abnormal	2		2				
CSF pressure decreased	1				1		
CSF pressure increased	9	4	9				
CSF protein	1		1				
CSF protein abnormal	2	1	2				
CSF protein decreased	2			2	2		
CSF protein increased	109	34	109				
CSF red blood cell count positive	6	4	6				
CSF test abnormal	26	12	26				
CSF virus identified	1		1				
CSF volume decreased	2	1	2				
CSF volume increased	3		1	1	2		
CSF white blood cell count increased	5	2	5				
Culture negative	1		1				
Culture positive	2		1	1	1		
Culture throat positive	1		1				
Culture urine positive	6		1	2	5		
Culture wound	1			1	1		
Cyst aspiration	1	1	1				
Cyst aspiration abnormal	1		1				

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cystatin C increased	3	1	1		2		
Cystoscopy	1		1				
Cytogenetic analysis abnormal	1		1				
Cytokine abnormal	2			1	2		
Cytokine increased	4		2	1	2		
Cytokine test	1		1				
Cytology abnormal	3	1	2		1		
Cytomegalovirus test positive	30	3	9	5	21		
Dehydroepiandrosterone increased	1				1		
Dengue virus test positive	6	2	2	3	4		
Dermatologic examination abnormal	2		1		1		
Differential white blood cell count	2		1		1		
Differential white blood cell count abnormal	9	1	3	3	6		1
Diffusion-weighted brain MRI abnormal	6	3	3	1	3		
Digestive enzyme abnormal	6			1	6		
Digestive enzyme decreased	2			2	2		
Disability assessment scale score increased	1		1				
DNA antibody positive	1				1		
Double stranded DNA antibody positive	2		1		1		
Drug clearance increased	1		1				
Drug level above therapeutic	1			1	1		
Drug level decreased	8	1	2	2	6		
Drug level fluctuating	1		1				
Drug level increased	9		3	2	6		
Drug screen positive	4		2		2		
Drug specific antibody	1				1		1
Drug specific antibody absent	2		1		1		

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Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Drug specific antibody present							1
Ear, nose and throat examination abnormal	4	1	1	1	3		
Eastern Cooperative Oncology Group performance status wc	2		1		1		
ECG P wave inverted	2	1	1	1	1		
ECG signs of myocardial ischaemia	1		1				
Echocardiogram	23		1	19	22		
Echocardiogram abnormal	72	2	11	42	61		
Echocardiogram normal	8		1	5	7		
Ejection fraction	6	2	4	1	2		
Ejection fraction abnormal	18	3	11	2	7		
Ejection fraction decreased	183	40	128	21	55	1	1
Electrocardiogram	46	1	2	33	44		
Electrocardiogram abnormal	664	69	205	257	459		1
Electrocardiogram ambulatory	4			4	4		
Electrocardiogram ambulatory abnormal	5	1	2	1	3		
Electrocardiogram change	33	8	22	3	11		
Electrocardiogram J wave abnormal	1	1	1				
Electrocardiogram J wave increased	1			1	1		
Electrocardiogram low voltage	6	1	2	2	4		
Electrocardiogram normal	28	1	2	16	26		
Electrocardiogram PR prolongation	7	4	5	1	2		
Electrocardiogram PR segment depression	24	1	2	8	22		
Electrocardiogram PR segment elevation	2		1		1		
Electrocardiogram PR shortened	11	2	11				
Electrocardiogram P wave abnormal	2			1	2		
Electrocardiogram QRS complex	1				1		
Electrocardiogram QRS complex abnormal	5	2	3	1	2		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Electrocardiogram QRS complex prolonged	14		14				
Electrocardiogram QRS complex shortened	22	5	22				
Electrocardiogram QT interval	1			1	1		
Electrocardiogram QT interval abnormal	3		3				
Electrocardiogram QT prolonged	46	14	46			1	1
Electrocardiogram QT shortened	1		1				
Electrocardiogram Q wave abnormal	10	5	10				
Electrocardiogram repolarisation abnormality	51	15	51				
Electrocardiogram R on T phenomenon	1		1				
Electrocardiogram ST segment	1			1	1		
Electrocardiogram ST segment abnormal	27	5	17	4	10		
Electrocardiogram ST segment depression	74	24	74				
Electrocardiogram ST segment elevation	395	137	395				
Electrocardiogram ST segment normal	1			1	1		
Electrocardiogram ST-T change	6	1	6				
Electrocardiogram ST-T segment abnormal	9	4	9				
Electrocardiogram ST-T segment depression	2		2				
Electrocardiogram ST-T segment elevation	4	1	4				
Electrocardiogram T wave abnormal	24	6	13	1	11		
Electrocardiogram T wave alternans	1	1	1				
Electrocardiogram T wave amplitude decreased	5	1	1	2	4		
Electrocardiogram T wave amplitude increased	3	1	3				
Electrocardiogram T wave inversion	89	39	89				1
Electrocardiogram T wave peaked	4	1	2		2		
Electroencephalogram abnormal	26	5	15	4	11		
Electromyogram abnormal	6	3	3		3		
Electrophoresis abnormal	4		1	2	3		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Electrophoresis protein abnormal	3			1	3		
Emergency care examination	3		1	1	2		
Endocrine test abnormal	1			1	1		
Endoscopy upper gastrointestinal tract	1			1	1		
Enterobacter test positive	1				1		
Enterococcus test positive	1				1		
Enterovirus test positive	1			1	1		
Enzyme activity increased	1				1		
Enzyme level abnormal	1				1		
Enzyme level increased	6		3		3		
Eosinophil count	2	1	1		1		
Eosinophil count abnormal	7	1	2	1	5		
Eosinophil count decreased	40		6	4	34		
Eosinophil count increased	125	15	52	22	73		
Eosinophil percentage abnormal	1		1				
Eosinophil percentage decreased	6		1		5		
Eosinophil percentage increased	10	1	3	1	7		
Epinephrine abnormal	4		1	2	3		
Epinephrine decreased	1		1				
Epinephrine increased	18	3	7	2	11		
Epstein-Barr virus antibody	2			2	2		
Epstein-Barr virus antibody positive	29		5	13	24		
Epstein-Barr virus antigen positive	4	1	2		2		
Epstein-Barr virus test positive	20	2	6	4	14		
Erythroblast count abnormal	1		1				
Erythroblast count increased	1				1		
Escherichia test positive	16	2	8	2	8		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Exercise electrocardiogram	1	1	1				
Exercise electrocardiogram abnormal	7	2	4	2	3		
Exercise electrocardiogram normal	1			1	1		
Face and mouth X-ray	1	1	1				
Faecal calprotectin	1		1				
Faecal calprotectin decreased	2			1	2		
Faecal calprotectin increased	27	5	10	4	17		
Faecal fat increased	2	1	1	1	1		
Faecal volume decreased	4			2	4		
Faecal volume increased	11	2	2	2	9		
False negative investigation result	1		1				
False negative pregnancy test	3		1	1	2		
False positive investigation result	11		2	2	9		
False positive tuberculosis test	1				1		
Female sex hormone level	2			1	2		
Female sex hormone level abnormal	5	1	3		2		
Femoral pulse	1			1	1		
FEV1/FVC ratio decreased	1	1	1				
Fibrin	1				1		
Fibrin abnormal	2		1	1	1		
Fibrin D dimer	21	1	2	11	19		
Fibrin D dimer decreased	10		3	2	7		
Fibrin D dimer increased	1973	243	837	460	1136	2	4
Fibrin D dimer normal	2			2	2		
Fibrin degradation products increased	20	4	14	2	6		
Fibrin increased	1			1	1		
Fibrinogen degradation products increased	2	1	1	1	1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Fibrinolysis	2	1	2				
Fibrinolysis abnormal	1		1				
Fibrinolysis increased	2		2				
Fibroblast growth factor 23	1				1		
Fibroblast growth factor 23 increased	1				1		
Foetal heart rate abnormal	45	14	42	2	3		
Foetal heart rate decreased	9	1	9			1	1
Foetal heart rate increased	2		2				
Foetal monitoring	1		1				
Foetal monitoring abnormal	2	1	1		1		
Foetal non-stress test	1				1		
Foetal non-stress test abnormal	1	1	1				
Forced expiratory flow	1		1				
Forced expiratory flow decreased	1		1				
Forced expiratory volume abnormal	1	1	1				
Forced expiratory volume decreased	1			1	1		
Forced expiratory volume increased	3	1	3				
Forced vital capacity decreased	1	1	1				
Foveal reflex abnormal	1		1				
Fractional exhaled nitric oxide abnormal	1		1				
Fractional exhaled nitric oxide normal	1				1		
Free prostate-specific antigen increased	1	1	1				
Free thyroxine index decreased	1		1				
Full blood count	5	1	2	2	3		
Full blood count abnormal	116	13	45	33	71	1	1
Full blood count decreased	14	2	5	5	9		
Full blood count increased	7	1	4		3		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Full blood count normal	4			4	4		
Functional residual capacity decreased	4	1	2	2	2		
Fungal test positive	9		5	1	4		
Gamma-glutamyltransferase	1		1				
Gamma-glutamyltransferase abnormal	11	3	6	4	5		
Gamma-glutamyltransferase decreased	9		4	1	5		
Gamma-glutamyltransferase increased	312	27	103	58	209		
Gastric pH	1	1	1				
Gastric pH decreased	29	4	7	9	22		
Gastrointestinal scan	1	1	1				
Gastrointestinal stoma output increased	1		1				
General physical condition	3		2		1		
General physical condition abnormal	108	14	40	33	68		
General physical condition normal	1				1		
Globulins decreased	1				1		
Globulins increased	6		2		4		
Glomerular filtration rate abnormal	6	1	2		4		
Glomerular filtration rate decreased	172	7	60	22	112		1
Glomerular filtration rate increased	14	2	3	3	11		1
Glucocorticoids abnormal	1			1	1		
Glucose tolerance increased	1				1		
Glucose tolerance test abnormal	1	1	1				
Glucose urine present	12	1	3		9		
Glutamate dehydrogenase decreased	1			1	1		
Glutamate dehydrogenase increased	2			1	2		
Glutathione s-transferase decreased	1			1	1		
Glycolysis increased	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glycosylated haemoglobin abnormal	4		2		2		
Glycosylated haemoglobin decreased	2				2		
Glycosylated haemoglobin increased	124	8	32	34	92		
Gram stain positive	1	1	1				
Granulocyte count decreased	9			5	9		
Granulocyte count increased	7	1	4	1	3		
Granulocyte percentage decreased	1				1		
Granulocyte percentage increased	1			1	1		
Granulocytes abnormal	2				2		
Grip strength	3		1		2		
Grip strength decreased	419	40	174	52	245	1	1
Gustometry	1				1		
Gynaecological examination	2	1	1		1		
Gynaecological examination normal	2			1	2		
Haematocrit abnormal	10	2	2	5	8		
Haematocrit decreased	144	9	30	20	114		1
Haematocrit increased	60	8	20	9	40		
Haematology test abnormal	7	2	5		2		
Haemoglobin	1		1				
Haemoglobin abnormal	22	4	10	4	12		1
Haemoglobin decreased	537	58	241	66	296	3	8
Haemoglobin distribution width increased	1			1	1		
Haemoglobin increased	64	4	24	13	40		
Haemoglobin urine	2		1		1		
Haemoglobin urine present	6		1	1	5		
Haptoglobin decreased	10	2	10				
Haptoglobin increased	5	1	3		2		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Head circumference abnormal	2		1		1		
Head lag	10	2	9		1		
Heart rate	234	35	115	33	119		
Heart rate abnormal	673	97	294	127	379		4
Heart rate decreased	1333	112	624	185	709	6	8
Heart rate increased	11499	1031	3868	2468	7631	16	35
Heart rate irregular	1985	262	787	503	1198	1	6
Heart rate normal	7		2	2	5		
Heart rate variability decreased	11	4	7	1	4		
Heart rate variability increased	16	8	14	1	2		
Heart sounds	7	2	4	1	3		
Heart sounds abnormal	47	5	20	8	27		
Heavy metal abnormal	1		1				
Heavy metal increased	1				1		
Helicobacter test	1				1		
Helicobacter test positive	9	1	3	1	6		1
Heparin-induced thrombocytopenia test positive	5		4		1		
Hepatic enzyme	1			1	1		
Hepatic enzyme abnormal	59	4	25	14	34		
Hepatic enzyme decreased	2	1	2			1	1
Hepatic enzyme increased	366	46	166	80	200	2	6
Hepatitis A antibody abnormal	1				1		
Hepatitis A antibody positive	4		1	1	3		
Hepatitis A virus test positive	2			1	2		
Hepatitis B antibody abnormal	1		1				
Hepatitis B antibody negative	1			1	1		
Hepatitis B antibody positive	2	1	1		1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hepatitis B core antibody positive	1			1	1		
Hepatitis B surface antibody positive	5		1	2	4		
Hepatitis B surface antigen positive	1				1		
Hepatitis B test negative	1			1	1		
Hepatitis B virus test positive	1				1		
Hepatitis C antibody positive	1			1	1		
Hepatitis C virus test positive	2	1	1		1		
Herpes simplex test positive	16		2	5	14		
Herpes virus test	1				1		
High density lipoprotein	1				1		
High density lipoprotein abnormal	2	2	2				
High density lipoprotein decreased	39		5	7	34		
High density lipoprotein increased	20		2	4	18		
Histamine abnormal	10	2	3	3	7		
Histamine level increased	20	2	6	6	14		
Histone antibody positive	1			1	1		
HIV antibody	1				1		
HIV antibody positive	6	1	1	2	5		
HIV antigen positive	1			1	1		
HIV test	1		1				
HIV test false positive	7			3	7		
HIV test negative	1		1				
HIV test positive	7		2	1	5		
HLA-B*27 positive	6		2	1	4		
Homans' sign	1				1		
Homans' sign positive	4			1	4		
Hoover's sign of leg paresis	1		1				

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System Organ Class

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hormone level abnormal	713	69	171	297	542		1
Human chorionic gonadotropin abnormal	1				1		
Human chorionic gonadotropin decreased	4		1	1	3		
Human chorionic gonadotropin increased	6		2	2	4		
Human chorionic gonadotropin positive	2				2		
Human epidermal growth factor receptor decreased	3		2		1		
Human epidermal growth factor receptor increased	2				2		
Human herpes virus 6 serology positive	1				1		
Human metapneumovirus test positive	1			1	1		
Human papilloma virus test negative	1			1	1		
Human papilloma virus test positive	4	1	3		1		
Human rhinovirus test positive	2			1	2		
Hypophonesis	1			1	1		
Hysteroscopy	1		1				
Iliac bruit	1		1				
Imaging procedure abnormal	2		1		1		
Imaging procedure artifact	1		1				
Immature granulocyte count increased	6		1		5		
Immunoglobulins	1		1				
Immunoglobulins abnormal	4		1		3		
Immunoglobulins decreased	3	1	1		2		
Immunoglobulins increased	19	1	5	2	14	1	1
Immunology test	5		1	2	4		
Immunology test abnormal	10	3	3	3	7		
Immunosuppressant drug level decreased	1				1		
Inflammation scan	1	1	1				
Inflammatory marker decreased	3	1	1		2		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Inflammatory marker increased	320	57	176	77	144	4	4
Inflammatory marker test	1			1	1		
Influenza A virus test positive	2	1	1	1	1		
Influenza B virus test positive	1				1		
Influenza virus test positive	1			1	1		
Inspiratory capacity abnormal	3				3		
Inspiratory capacity decreased	13	2	6	3	7		
Insulin C-peptide decreased	4		2		2		
Insulin tolerance test abnormal	1				1		
Intelligence test	1	1	1				
Interferon beta level increased	2	2	2				
Interferon gamma release assay positive	4		2		2		
Interleukin-2 receptor increased	8	2	2	1	6		
Interleukin level decreased	2			1	2		
Interleukin level increased	16	2	9	1	7		
International normalised ratio abnormal	33	3	17	6	16		
International normalised ratio decreased	87	3	32	9	55	1	1
International normalised ratio fluctuation	25	2	10	3	15		
International normalised ratio increased	252	7	127	19	125		
Intestinal transit time abnormal	3			2	3		
Intestinal transit time decreased	4			1	4		
Intestinal transit time increased	1				1		
Intra-abdominal pressure increased	1			1	1		
Intraocular pressure increased	146	20	57	34	89		
Intraocular pressure test	14	2	3	5	11		
Intraocular pressure test abnormal	18	2	5	6	13		
Investigation	3	1	1	2	2		

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Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Investigation abnormal	11	2	3	2	8	1	1
Iodine uptake decreased	3		1		2		
Iodine uptake increased	1		1				
Iron binding capacity total abnormal	2		1	1	1		
Iron binding capacity total decreased	1				1		
Iron binding capacity total increased	1		1				
Iron binding capacity unsaturated increased	2				2		
Joint position sense decreased	1		1				
KL-6 increased	2		1	1	1		
Klebsiella test positive	4		2	1	2		1
Laboratory test abnormal	86	12	37	14	49	1	2
Laboratory test interference	2				2		
Laboratory test normal	1				1		
Lactate dehydrogenase urine increased	1		1				
Lactobacillus test positive	1				1		
Laparoscopy abnormal	1		1				
Laryngoscopy	1			1	1		
Lasegue's test positive	2	1	1		1		
LE cells present	2			2	2		
Left ventricular end-diastolic pressure increased	5	1	3		2		
Legionella test positive	2			1	2		
Leucine aminopeptidase increased	3			1	3		
Leukocyte alkaline phosphatase increased	1		1				
Light chain analysis abnormal	1				1		
Light chain analysis increased	9		1	2	8		
Limb girth decreased	2		1		1		
Limb girth increased	3			3	3		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lipase abnormal	4		1	2	3		
Lipase decreased	6			1	6		
Lipase increased	97	5	30	21	67		
Lipids	1		1				
Lipids abnormal	11	1	3	3	8		
Lipids decreased	1			1	1		
Lipids increased	12		3	1	9		
Lipoprotein (a) increased	3				3		
Lipoprotein increased	2			1	2		
Listeria test positive	2				2		
Liver function test	1				1		
Liver function test abnormal	283	42	130	77	153		2
Liver function test decreased	7		2	2	5		
Liver function test increased	192	25	87	53	105		
Liver-kidney microsomal antibody positive	1	1	1				
Liver scan	1		1				
Liver scan abnormal	1		1				
Low density lipoprotein	1		1				
Low density lipoprotein abnormal	4	1	1	1	3		
Low density lipoprotein decreased	6		1		5		
Low density lipoprotein increased	126	3	17	23	109		1
Lumbar puncture	10		5	4	5		
Lumbar puncture abnormal	4		4				
Lung diffusion test abnormal	1	1	1				
Lung diffusion test decreased	2	2	2				
Lymph node palpable	175	4	19	37	156		
Lymph nodes scan abnormal	8		3	2	5		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lymphocyte count	4			1	4		
Lymphocyte count abnormal	14	1	3	3	11		
Lymphocyte count decreased	190	9	48	29	142	2	4
Lymphocyte count increased	103	9	26	24	77		
Lymphocyte morphology abnormal	23	1	6	4	17		
Lymphocyte percentage abnormal	3	1	1		2		
Lymphocyte percentage decreased	26	1	2	10	24		1
Lymphocyte percentage increased	9	1	1	3	8		
Lymphocyte stimulation test positive	2		1		1		
Lysozyme increased	2	1	1	1	1		
Magnetic resonance imaging	4		1	2	3		
Magnetic resonance imaging abdominal	1			1	1		
Magnetic resonance imaging abnormal	38	2	16	13	22	1	1
Magnetic resonance imaging breast abnormal	1				1		
Magnetic resonance imaging head	4	1	1		3		
Magnetic resonance imaging head abnormal	26	6	18	2	8		
Magnetic resonance imaging heart	5			3	5		
Magnetic resonance imaging spinal abnormal	6	1	4	1	2		
Male genital examination abnormal	1	1	1				
Mammogram abnormal	12	1	2	1	10		
Mast cell degranulation present	2		1		1		
Matrix metalloproteinase-3 increased	5		1		4		
Maximal voluntary ventilation	2		1		1		
Maximum heart rate	4	1	3		1		
Maximum heart rate increased	4	2	3		1		
Mean arterial pressure decreased	3		2		1		
Mean arterial pressure increased	9	1	3		6		

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mean cell haemoglobin	3		1		2		
Mean cell haemoglobin concentration	1				1		
Mean cell haemoglobin concentration abnormal	3	1	2	1	1		
Mean cell haemoglobin concentration decreased	36	1	3	4	33		
Mean cell haemoglobin concentration increased	23	2	2	6	21		
Mean cell haemoglobin decreased	32	1	3	7	29		2
Mean cell haemoglobin increased	21	1	2	2	19		
Mean cell volume abnormal	12	2	3	5	9		
Mean cell volume decreased	34		4	9	30		2
Mean cell volume increased	34	1	9	6	25		
Mean platelet volume decreased	14		4		10		
Mean platelet volume increased	20	1	3	8	17		
Measles antibody positive	1			1	1		
Megakaryocytes	1			1	1		
Megakaryocytes abnormal	1			1	1		
Megakaryocytes increased	3		2		1		
Menstruation normal	41		4	16	37		
Metabolic function test abnormal	5		1	1	4		
Metamyelocyte count increased	4		2		2		
Metamyelocyte percentage increased	2			1	2		
Mini mental status examination abnormal	1		1				
Misleading laboratory test result	1				1		
Monoblast count decreased	2		1		1		
Monoblast count increased	2				2		
Monoclonal immunoglobulin increased	1		1				
Monoclonal immunoglobulin present	4			2	4		
Monocyte count abnormal	8	2	2	3	6		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Monocyte count decreased	26		7	4	19		
Monocyte count increased	105	5	19	23	86		
Monocyte percentage abnormal	2		1		1		
Monocyte percentage decreased	2		1		1		
Monocyte percentage increased	15		1	4	14		1
Mononuclear cell count increased	4		3		1		
Mumps antibody test positive	1				1		
Muscle enzyme	1				1		
Muscle enzyme increased	6		3	1	3		
Muscle strength abnormal	91	8	28	32	63	1	1
Mycobacterium tuberculosis complex test positive	2			1	2		
Mycoplasma test positive	10	1	4	3	6		
Myelocyte count decreased	1				1		
Myelocyte count increased	5		2	1	3		
Myocardial necrosis marker	1		1				
Myocardial necrosis marker increased	144	56	144				1
Myocardial strain imaging	7		3		4		
Myocardial strain imaging abnormal	5	2	2	1	3		
Myoglobin blood decreased	3	1	1		2		
Myoglobin blood increased	22	5	16	2	6		
Nasopharyngeal swab	1		1				
Natural killer cell activity decreased	1				1		
Natural killer cell count decreased	3			3	3		
Natural killer cell count increased	1			1	1		
Natural killer T cell count decreased	1	1	1				
Natural killer T cell count increased	3				3		
Nerve conduction studies	1				1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nerve conduction studies abnormal	19		9	4	10		
Nerve stimulation test abnormal	1				1		
Neurological examination abnormal	17		4	5	13		
Neurological examination normal	3			1	3		
Neurone-specific enolase increased	2	1	2				
Neurotransmitter level altered	1				1		
Neutralising antibodies negative	3			1	3		
Neutrophil count	3		2		1		
Neutrophil count abnormal	21	1	7	5	14		1
Neutrophil count decreased	129	17	57	22	72		
Neutrophil count increased	226	8	59	33	167		1
Neutrophil gelatinase-associated lipocalin increased	1		1				
Neutrophil/lymphocyte ratio decreased	1				1		
Neutrophil/lymphocyte ratio increased	1			1	1		
Neutrophil morphology abnormal	1		1				
Neutrophil percentage abnormal	3	2	2		1		
Neutrophil percentage decreased	10		2	2	8		
Neutrophil percentage increased	24	2	5	7	19		1
NIH stroke scale abnormal	1				1		
NIH stroke scale score decreased	2		1		1		
NIH stroke scale score increased	1				1		
Nitrite urine present	8		2		6		1
Non-high-density lipoprotein cholesterol increased	6			2	6		
Norepinephrine increased	3				3		
Norovirus test positive	1				1		
N-terminal prohormone brain natriuretic peptide	1	1	1				
N-terminal prohormone brain natriuretic peptide decreased	1			1	1		

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		I	C	I	C	I	C
N-terminal prohormone brain natriuretic peptide increased	142	36	86	20	56		
Nutritional assessment	1			1	1		
Nutritional condition abnormal	2			2	2	1	1
NYHA classification	1		1				
Occult blood	1		1				
Occult blood positive	12	1	5		7		
Oculomotor study abnormal	1	1	1				
Oesophagogastroscopy normal	1				1		
Oestradiol abnormal	1		1				
Oestradiol decreased	2			2	2		
Oestradiol increased	8	1	1	2	7		
Ophthalmological examination	1	1	1				
Ophthalmological examination abnormal	3			1	3		
Opiates	1				1		
Opiates positive	1		1				
Orthopaedic examination abnormal	2		1		1		
Orthostatic heart rate response increased	1				1		
Osmolar gap increased	1				1		
Osteoprotegerin ligand decreased	1				1		
Oxygen consumption decreased	27	2	8	9	19	1	1
Oxygen consumption increased	4	1	2	1	2		
Oxygen saturation	18	3	10	1	8		
Oxygen saturation abnormal	96	11	41	16	55		1
Oxygen saturation decreased	2765	266	1942	173	823	5	21
Oxygen saturation immeasurable	9		8	1	1		
Oxygen saturation increased	12		5	3	7		
Oxygen saturation normal	1				1		

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		I	C	I	C	I	C
Pain assessment	3		1	1	2		
Pain threshold decreased	5	1	2	1	3		
Palpatory finding abnormal	3		1		2		
Pancreatic enzymes decreased	2			1	2		
Pancreatic enzymes increased	17	5	14		3		
PaO2/FiO2 ratio decreased	1		1				
Paracentesis	1				1		
Parasite stool test positive	2				2		
Parasitic test positive	1		1				
Parvovirus B19 test positive	6		1		5		
Pathology test	1			1	1		
PCO2 abnormal	1		1				
PCO2 decreased	16	2	7	2	9		
PCO2 increased	15	2	4	4	11		
Peak expiratory flow rate	1		1				
Peak expiratory flow rate abnormal	3	1	3				
Peak expiratory flow rate decreased	20	4	20				
Pedal pulse abnormal	1		1				
Perfusion brain scan abnormal	1				1		
Peripheral pulse decreased	5	1	4		1		
Phalen's test positive	2		1	1	1		
pH body fluid	1	1	1				
pH body fluid abnormal	3			1	3		
pH body fluid decreased	2			1	2		
pH body fluid increased	1		1				
Philadelphia chromosome positive	2	2	2				
pH urine	4		1		3		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
pH urine abnormal	1		1				
pH urine increased	8	1	2	2	6		
Physical capacity evaluation	2			1	2		
Physical examination abnormal	2		1		1		
Pituitary scan abnormal	1				1		
Placenta growth factor	1	1	1				
Plasma cells increased	1				1		
Plasma viscosity abnormal	2		2				
Platelet aggregation abnormal	4		2		2		
Platelet aggregation increased	4	1	2		2		
Platelet count	2				2		
Platelet count abnormal	33	6	15	6	18		1
Platelet count decreased	1006	116	541	131	465	1	8
Platelet count increased	249	20	71	54	178		2
Platelet count normal	1		1				
Plateletcrit abnormal	1		1				
Plateletcrit decreased	3			2	3		
Plateletcrit increased	2		1		1		
Platelet distribution width decreased	7		1	1	6		
Platelet distribution width increased	3		1		2		
Platelet factor 4	2		2				
Platelet factor 4 decreased	1		1				
Platelet factor 4 increased	2		2				
Platelet function test abnormal	3	1	1	1	2		
Platelet morphology abnormal	6			1	6		
Pleural fluid analysis abnormal	3	2	3				
PO2 abnormal	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
PO2 decreased	43	7	25	3	18		
PO2 increased	7		3	1	4		
Polymerase chain reaction	4		2		2		
Polymerase chain reaction positive	21		8	2	13		
Positron emission tomogram abnormal	5			2	5		
Prealbumin decreased	1		1				
Pregnancy test	2				2		
Pregnancy test false positive	2		1	1	1		
Pregnancy test negative	7			2	7		
Pregnancy test positive	2				2		
Pregnancy test urine negative	1		1				
Procalcitonin abnormal	2			1	2		
Procalcitonin decreased	5				5		
Procalcitonin increased	35	3	17	2	18		
Product residue present	4	1	2		2		
Progesterone abnormal	3			1	3		
Progesterone decreased	14	2	3	7	11		
Progesterone increased	3		1	2	2		
Prohormone brain natriuretic peptide abnormal	1			1	1		
Prohormone brain natriuretic peptide increased	10	2	5	1	5		
Promyelocyte count increased	1			1	1		
Prostate examination abnormal	1				1		
Prostatic specific antigen decreased	9			4	9		
Prostatic specific antigen increased	77	11	26	26	51		
Protein albumin ratio	1			1	1		
Protein C decreased	3	1	1	1	2		
Protein C increased	25	5	13	4	12		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Protein S abnormal	1		1				
Protein S decreased	5	2	3	2	2		
Protein S increased	2		1	1	1		
Protein total abnormal	7	2	4		3		
Protein total decreased	53		8	9	45		1
Protein total increased	34	3	11	3	23		
Protein urine	22	3	9	6	13		
Protein urine absent	1		1				
Protein urine present	77	4	28	20	49		
Proteus test positive	2		1		1		
Prothrombin consumption time shortened	1				1		
Prothrombin level abnormal	3		1	1	2		
Prothrombin level decreased	8	1	4	2	4		
Prothrombin level increased	7	1	4		3		
Prothrombin time abnormal	8	2	2	5	6		
Prothrombin time prolonged	51	2	18	8	33	1	1
Prothrombin time ratio abnormal	1			1	1		
Prothrombin time ratio decreased	6		2	1	4		
Prothrombin time ratio increased	10		2	3	8		
Prothrombin time shortened	33	2	10	6	23		
Pseudomonas test positive	2		1	1	1		
Psoriasis area severity index decreased	2		1		1		
Pulmonary arterial pressure abnormal	1		1				
Pulmonary arterial pressure increased	24	3	13	4	11		
Pulmonary arterial wedge pressure decreased	1				1		
Pulmonary arterial wedge pressure increased	1		1				
Pulmonary function test	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pulmonary function test abnormal	6	3	4	1	2		
Pulmonary function test decreased	69	14	27	22	42		1
Pulmonary imaging procedure abnormal	1			1	1		
Pulmonary physical examination abnormal	1		1				
Pulse abnormal	364	31	136	97	228		
Pulse absent	91	12	65	8	26		
Pulse pressure abnormal	2			1	2		
Pulse pressure decreased	10	1	6	1	4		
Pulse pressure increased	23	2	4	8	19		
Pulse volume decreased	21		7		14		
Pulse waveform abnormal	4			1	4		
Pupil dilation procedure	1			1	1		
Pupillary light reflex tests abnormal	4	1	4				
Pus in stool	1		1				
Pyruvate kinase increased	2				2		
QRS axis abnormal	10	2	4	5	6		
Quality of life decreased	528	69	179	161	349	2	3
Radial pulse abnormal	26		20	2	6		
Radial pulse decreased	5		3	1	2		
Radial pulse increased	3	1	2		1		
Radioisotope uptake increased	1		1				
Red blood cell analysis abnormal	1	1	1				
Red blood cell anisocytes present	1		1				
Red blood cell count abnormal	12	3	5	4	7		
Red blood cell count decreased	189	16	51	30	138	1	2
Red blood cell count increased	69	9	14	14	55		
Red blood cell morphology abnormal	4	3	3	1	1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Red blood cell nucleated morphology	1				1		
Red blood cell rouleaux formation present	2		1	1	1		
Red blood cell schistocytes present	1	1	1				
Red blood cell sedimentation rate	1				1		
Red blood cell sedimentation rate abnormal	19	2	10	5	9		
Red blood cell sedimentation rate decreased	13		2	2	11		
Red blood cell sedimentation rate increased	369	35	125	80	244		
Red blood cells urine	5	1	3		2		
Red blood cells urine positive	20	1	8	4	12		1
Red cell distribution width abnormal	1	1	1				
Red cell distribution width decreased	12	1	3	2	9		
Red cell distribution width increased	37		7	8	30		1
Renal function test abnormal	39	13	20	7	19		
Renin	1				1		
Renin increased	4			3	4		
Respiratory rate	6		1	3	5		
Respiratory rate decreased	114	11	55	18	59		
Respiratory rate increased	463	27	221	71	242	3	5
Respiratory sinus arrhythmia magnitude	1				1		
Respiratory sinus arrhythmia magnitude abnormal	1		1				
Respiratory syncytial virus test positive	3	1	1	1	2		
Reticulocyte count decreased	3		1		2		
Reticulocyte count increased	8	2	5	2	3		
Reticulocyte percentage increased	1				1		
Retinogram abnormal	2		2				
Rhesus antibodies positive	2		1		1		
Rhesus antigen negative	1			1	1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Rhesus antigen positive	1	1	1				
Rheumatoid factor	3			2	3		
Rheumatoid factor increased	68	9	27	22	41		
Rheumatoid factor positive	27	4	12	6	15		
Right atrial volume abnormal	1		1				
Right atrial volume decreased	1			1	1		
Right ventricular ejection fraction decreased	1	1	1				
Right ventricular systolic pressure increased	2		2				
Rinne tuning fork test abnormal	1				1		
Romberg test positive	15	4	8	2	7		
Roseolovirus test positive	2			1	2		
Rubella antibody positive	2			1	2		
Rubivirus test positive	1				1		
Rubulavirus test positive	2				2		
Salmonella test positive	3		2	1	1		
SARS-CoV-1 test negative	2			2	2		
SARS-CoV-1 test positive	4		1		3		
SARS-CoV-2 antibody test	20		3	14	17		
SARS-CoV-2 antibody test negative	399	1	28	249	371		
SARS-CoV-2 antibody test positive	101	4	14	3	87		
SARS-CoV-2 test	7	1	5	1	2		
SARS-CoV-2 test false negative	2			1	2		
SARS-CoV-2 test false positive	17	1	4	1	13		
SARS-CoV-2 test negative	97	3	27	54	70		
SARS-CoV-2 test positive	1061	155	809	24	252	9	28
Scan abdomen abnormal	1		1				
Scan abnormal	2		1		1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Scan gallium abnormal	1		1				
Scan lymph nodes	3		1		2		
Scan myocardial perfusion abnormal	1		1				
Schellong test	1			1	1		
Schirmer's test abnormal	1				1		
Semen analysis abnormal	2				2		
Semen viscosity decreased	1				1		
Semen viscosity increased	1				1		
Semen volume abnormal	1				1		
Semen volume decreased	4			1	4		
Semen volume increased	2			1	2		
Sensory level	4	1	2	1	2		
Sensory level abnormal	202	24	44	92	158	1	1
Seroconversion test negative	4		2		2		
Serology abnormal	1			1	1		
Serology negative	3			1	3		
Serratia test positive	2		1		1		
Serum amyloid A protein increased	1				1		
Serum colour abnormal	1		1				
Serum ferritin	1		1				
Serum ferritin abnormal	8	1	6	2	2		
Serum ferritin decreased	78	19	40	17	38		
Serum ferritin increased	157	22	56	31	101		
Shift to the left	3		1	1	2		
Shift to the right	1				1		
Sigmoidoscopy abnormal	1		1				
Sinus rhythm	55	6	20	13	35	1	1

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skin temperature	39	3	20	3	19		
Skin test positive	24	2	5	10	19		
Skin turgor decreased	4		2	1	2		
Skull X-ray	2		1		1		
Slow vital capacity	1				1		
Smear cervix	2		1		1		
Smear cervix abnormal	10	1	2	2	8		
Smooth muscle antibody positive	4	2	4				
Soluble fibrin monomer complex increased	1		1				
Somatosensory evoked potentials abnormal	3		1	1	2		
Specific gravity urine decreased	3		1		2		
Specific gravity urine increased	3	1	1		2		
Sperm analysis abnormal	1				1		
Spermatozoa abnormal	4				4		
Sperm concentration abnormal	2		2				
Sperm concentration decreased	6	1	4	2	2		
Sperm concentration increased	1				1		
Spinal myelogram abnormal	1			1	1		
Spirometry abnormal	3	1	2		1		
Sputum abnormal	30	1	9	7	21		
Sputum normal	1				1		
Staphylococcus test positive	9		4	3	5		
Stenotrophomonas test positive	2	1	2				
Streptobacillus test positive	1			1	1		
Streptococcus test positive	15	1	8	1	7		
Stress echocardiogram abnormal	2		1	1	1		
Stroke volume decreased	2	1	2				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Strongyloides test positive	1				1		
Sweat test	1		1				
Swollen joint count	1		1				
Swollen joint count increased	1		1				
Synovial fluid analysis abnormal	1		1				
Synovial fluid crystal present	2			1	2		
Synovial fluid white blood cells positive	2		2				
Systemic lupus erythematosus disease activity index abnorm	1		1				
Systemic lupus erythematosus disease activity index decrea	1				1		
Tandem gait test abnormal	2			1	2		
Temperature difference of extremities	30	5	16	4	14		1
Temperature perception test abnormal	8		4	2	4		
Temperature perception test decreased	8	1	1	5	7		
Temperature perception test increased	13		1	7	12		
Tender joint count	2		1		1		
Thermometry abnormal	3			1	3		
Thrombin-antithrombin III complex abnormal	1			1	1		
Thrombin-antithrombin III complex increased	1		1				
Thyroglobulin increased	8	1	4	1	4		
Thyroid function test abnormal	36	2	9	7	27		1
Thyroid function test normal	2	1	1	1	1		
Thyroid gland scan abnormal	2		1		1		
Thyroid hormones decreased	9	3	4	4	5		
Thyroid hormones increased	41	9	15	15	26		
Thyroid stimulating immunoglobulin	1			1	1		
Thyroid stimulating immunoglobulin increased	3		1	1	2		
Thyroxine	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thyroxine abnormal	3		1	2	2		
Thyroxine decreased	8	2	2	1	6		
Thyroxine free abnormal	3			3	3		
Thyroxine free decreased	12		1	7	11		
Thyroxine free increased	21	3	8	7	13		
Thyroxine increased	22		4	5	18		
Tidal volume decreased	1		1				
Tilt table test positive	1		1				
T-lymphocyte count decreased	4		1	2	3		
T-lymphocyte count increased	11	2	2	3	9		
Total bile acids increased	3		1	1	2		
Total cholesterol/HDL ratio abnormal	1				1		
Total cholesterol/HDL ratio decreased	2			1	2		
Total cholesterol/HDL ratio increased	5			2	5		
Total complement activity decreased	2		1	1	1		
Total complement activity increased	4		2		2		
Total complement activity test	1			1	1		
Total lung capacity abnormal	3		2		1		
Total lung capacity decreased	44	6	18	14	26		
Total neuropathy score	1	1	1				
Total sperm count decreased	1			1	1		
Toxicologic test abnormal	2			2	2		
Toxoplasma serology positive	2				2		
Transaminases	2	1	1	1	1		
Transaminases abnormal	6	2	3	2	3		
Transaminases decreased	2		1		1		
Transaminases increased	211	31	83	41	128		

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System Organ Class

Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Transferrin abnormal	2		1	1	1		
Transferrin decreased	8	1	3		5		
Transferrin increased	5	1	2	1	3		
Transferrin saturation	1	1	1				
Transferrin saturation abnormal	2			2	2		
Transferrin saturation decreased	9	1	4	3	5		
Transferrin saturation increased	3		1	1	2		
Treponema test false positive	1			1	1		
Treponema test positive	8	1	1		7		
Tri-iodothyronine	1				1		
Tri-iodothyronine abnormal	1	1	1				
Tri-iodothyronine decreased	12		6	2	6		
Tri-iodothyronine free abnormal	1			1	1		
Tri-iodothyronine free decreased	6			3	6		
Tri-iodothyronine free increased	12		2	5	10		
Tri-iodothyronine increased	11		3	5	8		
Troponin	54	1	3	41	51		
Troponin abnormal	89	12	38	21	51		
Troponin decreased	18	2	8	4	10		
Troponin I	3	1	1	1	2		
Troponin I abnormal	7	3	4	2	3		
Troponin I decreased	5		1	2	4		
Troponin I increased	225	44	128	34	97	1	1
Troponin increased	1353	204	648	288	705	1	3
Troponin I normal	1				1		
Troponin normal	2			1	2		
Troponin T	1			1	1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Troponin T increased	192	44	133	21	59		
Tryptase decreased	3				3		
Tryptase increased	6		3	1	3		
Tuberculin test positive	5		3	1	2		
Tumour marker abnormal	3	1	2	1	1		
Tumour marker decreased	7			4	7		
Tumour marker increased	32	3	12	6	20		
Tympanometry abnormal	2	2	2				
Ultrasound abdomen abnormal	1			1	1		
Ultrasound breast abnormal	3		1	1	2		
Ultrasound Doppler abnormal	2			1	2	1	1
Ultrasound foetal abnormal	2	1	2				
Ultrasound kidney abnormal	1			1	1		
Ultrasound liver abnormal	2			1	2		
Ultrasound ovary abnormal	1				1		
Ultrasound scan	1			1	1		
Ultrasound scan abnormal	6		2	1	4		
Ultrasound scan normal	1				1		
Ultrasound thyroid abnormal	1		1				
Ultrasound uterus abnormal	1			1	1		
Unevaluable specimen	1		1				
Urea urine	1				1		
Urea urine abnormal	2		1	1	1		
Urea urine decreased	1		1				
Urea urine increased	1	1	1				
Urinary lipids present	1				1		
Urinary occult blood	10	3	7	2	3		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Urinary occult blood positive	20		8	3	12		
Urinary sediment abnormal	5			4	5		
Urinary sediment present	5	1	2		3		
Urine albumin/creatinine ratio increased	6	1	4	2	2		
Urine analysis abnormal	66	6	22	9	44		3
Urine bilirubin decreased							1
Urine bilirubin increased							1
Urine calcium increased	1	1	1				
Urine chromium increased	1		1				
Urine copper	4	1	3		1		
Urine copper increased	1	1	1				
Urine cytology	1		1				
Urine cytology abnormal	3	1	2	1	1		
Urine ketone body	3		1		2		
Urine ketone body present	20	2	10	2	10		1
Urine leukocyte esterase positive	6	1	2		4		1
Urine output	11		5	1	6		
Urine output decreased	110	17	57	10	53		
Urine output increased	33	3	9	4	24		
Urine oxalate increased							1
Urine porphobilinogen increased	1		1				
Urine potassium decreased	2		1	1	1		
Urine protein/creatinine ratio increased	6	1	2	3	4		
Urine sodium abnormal	1				1		
Urine sodium decreased	2	1	1	1	1		
Urine sodium increased	2		2				
Urine uric acid increased	1		1				

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System Organ Class

Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Urobilinogen urine increased	7			2	7		
Vaccine induced antibody absent	8	2	2	2	6		
Vaginal pH abnormal	1		1				
Vaginal pH increased	1				1		
Varicella virus test positive	23	1	7	5	16		
Vascular resistance pulmonary	1	1	1				
Vascular resistance pulmonary increased	1		1				
Vascular test abnormal	2		1		1		
Venogram	1		1				
Venogram abnormal	1		1				
Venous bruit	1				1		
Venous oxygen partial pressure decreased	2			2	2		
Venous oxygen saturation decreased	8		5	2	3		
Venous pressure	1				1		
Venous pressure increased	1				1		
Venous pressure jugular	1			1	1		
Venous pressure jugular increased	4	1	1	2	3		
Ventilation/perfusion scan	1	1	1				
Ventricular internal diameter abnormal	1	1	1				
Very low density lipoprotein increased	1			1	1		
Vestibular function test abnormal	5	1	5				
Vibration test abnormal	3		1	1	2		
Viral load	2	1	1		1		
Viral test	2		2				
Viral test positive	5		1	2	4		
Visual acuity tests	1		1				
Visual analogue scale	28	1	3	21	25		

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Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Visual evoked potentials abnormal	2	1	1		1		
Visual field tests abnormal	2				2		
Visual field tests normal	1	1	1				
Visual tracking test abnormal	1			1	1		
Vital capacity	1		1				
Vital capacity decreased	3		1		2		
Vital functions abnormal	11	1	5	3	6		
Vital signs measurement	1				1		
Vitamin B12 abnormal	5		3		2		
Vitamin B12 decreased	48	3	15	11	33	1	2
Vitamin B12 increased	24	6	10	3	14		
Vitamin B1 decreased	1				1		
Vitamin B1 increased	1				1		
Vitamin B6 decreased	2			1	2		
Vitamin B6 increased	4	1	1		3		
Vitamin D	1		1				
Vitamin D abnormal	3	2	2	1	1		
Vitamin D decreased	80	7	12	27	68		1
Vitamin D increased	2			1	2		
Vitamin K increased	1	1	1				
Volume blood	1				1		
Volume blood decreased	1		1				
Von Willebrand's factor activity decreased	2	1	2				
Von Willebrand's factor activity increased	5		3	2	2		
Von Willebrand's factor antigen increased	1			1	1		
Waist circumference increased	8	3	5	2	3		
Walking distance test abnormal	2			1	2		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Wall motion score index abnormal	4	1	2	2	2		
Weber tuning fork test abnormal	3			1	3		
Weight	1				1		
Weight abnormal	13	1	3	3	10		1
Weight decreased	3151	444	1175	832	1976	14	27
Weight increased	827	76	200	274	627	7	14
West Nile virus test positive	1		1				
White blood cell analysis abnormal	1			1	1		
White blood cell count	4		1	1	3		
White blood cell count abnormal	32	10	19	5	13		1
White blood cell count decreased	405	28	138	71	267		5
White blood cell count increased	835	58	311	132	524	1	3
White blood cell count normal	1				1		
White blood cell morphology abnormal	2	1	1		1		
White blood cells urine	16		4	4	12		
White blood cells urine positive	39		9	9	30		3
X-ray abnormal	8	2	4		4		
X-ray gastrointestinal tract abnormal	1		1				
X-ray limb abnormal	1				1		
X-ray with contrast upper gastrointestinal tract	1		1				
Total:	96411	8392	33798	20838	62613	177	438

System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal loss of weight	135	29	77	36	58		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal weight gain	41	6	21	11	20		
Acetonaemia	8		5	1	3		
Acidosis	42	8	31	4	11		
Acidosis hyperchloraemic	1		1				
Adult failure to thrive	6	2	6				
Alcoholic ketoacidosis	1		1				
Alcohol intolerance	46	6	14	12	32		
Alkalosis	8	1	2	2	6		
Appetite disorder	178	10	36	48	142	1	1
Body fat disorder	2				2		
Breast milk substitute intolerance	1		1				
Cachexia	56	13	56				1
Calcification metastatic	1			1	1		
Calcium deficiency	3		2	1	1		
Calcium metabolism disorder						1	1
Carbohydrate intolerance	4	1	2	2	2		
Cell death	42	5	21	9	21	1	1
Central obesity	2			1	2		
Cerebral salt-wasting syndrome	2		2				
Cholesterosis	1		1				
Chvostek's sign	1		1				
Copper deficiency	1				1		
Dairy intolerance	12	2	6	3	6		1
Decreased appetite	13410	929	3648	2629	9762	9	34
Decreased insulin requirement	8		2		6		
Dehydration	1631	162	819	186	812	5	8
Diabetes mellitus	439	155	439			15	28

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Diabetes mellitus inadequate control	237	66	237			1	1
Diabetic complication	7		6	1	1		
Diabetic ketoacidosis	106	38	106				
Diabetic ketosis	6	1	6				
Diabetic metabolic decompensation	33	9	33				
Diet refusal	15	1	10	2	5		
Dyslipidaemia	59	8	21	16	38		
Eating disorder symptom	25		8	4	17		
Electrolyte depletion	3		1		2		
Electrolyte imbalance	61	10	33	10	28		
Enzyme abnormality	5		1		4		
Failure to thrive	6	1	6				
Fat intolerance	1				1		
Feeding disorder	868	106	398	83	470	1	3
Feeding intolerance	7	1	1	1	6		
Fluid imbalance	9		4	2	5		
Fluid intake reduced	70	8	36	6	34		
Fluid retention	463	36	151	110	312		1
Folate deficiency	66	11	25	17	41		
Food aversion	110	11	28	23	82		1
Food craving	82	4	16	24	66		1
Food intolerance	156	23	52	64	104		
Food refusal	50	8	32	4	18		
Fructose intolerance	3		1	2	2		
Fulminant type 1 diabetes mellitus	7	4	7				
Galactose intolerance	1	1	1				
Glucose tolerance impaired	36	5	14	7	22		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glucose tolerance impaired in pregnancy	1				1		
Gluten sensitivity	35	7	17	8	18		
Glycopenia	1				1		
Gout	532	29	164	90	368		
Haemochromatosis	7	1	3	2	4		
Haemosiderosis	4	3	3		1		
Histamine intolerance	85	17	25	36	60		
Hyperalbuminaemia	1		1				
Hyperammonaemia	4	1	2	2	2		
Hyperamylasaemia	3			2	3		
Hypercalcaemia	32	7	22	5	10		
Hypercarotinaemia	1		1				
Hypercatabolism	1		1				
Hyperchloraemia	4		1	2	3		
Hypercholesterolaemia	92	14	36	20	56		1
Hypercreatininaemia	5	1	3		2		
Hyperferritinaemia	30	3	9	10	21		
Hyperglycaemia	526	43	248	78	278	1	3
Hyperglycaemic hyperosmolar nonketotic syndrome	8	1	8				
Hyperhomocysteinaemia	13	3	6	1	7		
Hyperinsulinaemic hypoglycaemia	1	1	1				
Hyperkalaemia	97	20	97				2
Hyperlactacidaemia	18	2	14	2	4		
Hyperlipasaemia	14	1	4	7	10		
Hyperlipidaemia	45	9	17	10	28		
Hypermagnesaemia	1		1				
Hypermetabolism	21	1	4	8	17		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypematraemia	56	7	34	6	22	1	1
Hyperphagia	31	1	16	1	15		
Hyperphosphataemia	2		1	1	1		
Hyperproteinaemia	8		2	3	6		
Hypertriglyceridaemia	32	3	8	13	24		
Hyperuricaemia	32	3	17	7	15		
Hypervitaminosis	1				1		
Hypervitaminosis B	1		1				
Hypervitaminosis B12	2		1		1		
Hypervolaemia	39	6	23	5	16		
Hypoalbuminaemia	73	11	43	11	30	1	1
Hypocalcaemia	38	4	27	3	11		
Hypochloraemia	9		8	1	1		
Hypocholesterolaemia	2			2	2		
Hypoferritinaemia	4			2	4		
Hypoglycaemia	621	45	281	86	340	2	4
Hypoglycaemia neonatal	4		4				1
Hypoglycaemia unawareness	2		1		1		
Hypokalaemia	309	93	309			3	4
Hypokalaemic syndrome	5		2	1	3		
Hypomagnesaemia	13	2	8	1	5		
Hypometabolism	8	3	3	4	5		
Hyponatraemia	270	46	168	30	102		1
Hyponatraemic syndrome	5		3		2		
Hypophagia	287	31	145	80	142	1	1
Hypophosphataemia	18	2	8	2	10	1	1
Hypoproteinaemia	16	5	10	2	6		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypovitaminosis	31	3	14	9	17		
Hypovolaemia	15	3	9	4	6		
Hypozincaemia	1			1	1		
Impaired fasting glucose	8	1	4	1	4		
Impaired insulin secretion	2		1		1		
Increased appetite	221	7	25	54	196		2
Increased insulin requirement	36	5	11	12	25		
Insulin-requiring type 2 diabetes mellitus	1		1				
Insulin resistance	41	8	19	6	22		
Insulin resistant diabetes	2		2				
Iron deficiency	153	19	44	65	109	1	1
Iron overload	4		1	1	3		
Ketoacidosis	32	8	32				
Ketosis	4		2	1	2		
Ketosis-prone diabetes mellitus	1	1	1				
Lack of satiety	3			1	3		
Lactic acidosis	40	5	40				
Lactose intolerance	42	4	12	11	30		
Latent autoimmune diabetes in adults	9	2	8	1	1		
Lipid metabolism disorder	4	1	1	2	3		
Lipoedema	30	15	30				
Lipomatosis	3		2		1		
Macroamylasaemia	1		1				
Magnesium deficiency	4		1	2	3		
Malnutrition	77	15	41	17	36		
Marasmus	31	4	30	1	1		
Metabolic acidosis	83	15	64	4	19		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Metabolic alkalosis	6			2	6		
Metabolic disorder	39	5	13	13	26		
Metabolic syndrome	6	1	3	2	3		
Mineral deficiency	4		1	2	3		
Mineral metabolism disorder	9	1	5	4	4		
Mitochondrial cytopathy	5	5	5				
Neonatal hypocalcaemia	1	1	1				
Neonatal hyponatraemia	1	1	1				
Neonatal insufficient breast milk syndrome	14	1	4	8	10		
Obesity	28	3	9	6	19		
Oligodipsia	9		1	4	8		
Overfeeding of infant	1				1		
Overweight	20		4	3	16		
Pancreatogenous diabetes	1	1	1				
Periarthritis calcarea	1		1				
Polydipsia	130	4	32	23	98		
Poor feeding infant	80	4	16	41	64		1
Postprandial hypoglycaemia	4	1	2	1	2		
Propofol infusion syndrome	1	1	1				
Protein deficiency	4	1	1	2	3		
Pseudo-Bartter syndrome	1				1		
Salt craving	9	1	3	2	6		
Salt intoxication	1				1		
Selenium deficiency	1		1				
Shock hypoglycaemic	3	1	3				
Sodium retention	1		1				
Starvation	5		5				

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Steroid diabetes	1		1				
Tetany	115	9	53	26	62		
Trace element deficiency	1		1				
Trousseau's sign	2		2				
Tumour lysis syndrome	3	3	3				
Type 1 diabetes mellitus	228	116	228			3	3
Type 2 diabetes mellitus	116	58	116				3
Underweight	12	2	4	3	8		
Vitamin B12 deficiency	56	6	22	17	34		
Vitamin B1 deficiency	3		1	1	2		
Vitamin B6 deficiency	5		1	3	4		
Vitamin B complex deficiency	5	1	3	1	2		
Vitamin C deficiency	4		1		3		
Vitamin D deficiency	133	16	45	27	88		
Water intoxication	3	2	3				
Weight fluctuation	24		1	5	23		
Weight gain poor	6		1	4	5		
Weight loss poor	9	1	4		5		
Zinc deficiency	4	1	1	3	3		
Total:	24038	2470	9240	4262	14798	48	112

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute aseptic arthritis	10	1	10				
Amplified musculoskeletal pain syndrome	3			2	3		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Amyotrophy	34	18	34				
Ankle deformity	1				1		
Ankylosing spondylitis	200	89	200			11	23
Antisynthetase syndrome	19	4	14	3	5		
Arthralgia	121356	4589	17837	24576	103519	112	310
Arthritis	2754	371	1055	599	1699	8	15
Arthritis allergic	2		1	1	1		
Arthritis enteropathic	1		1				
Arthritis reactive	287	109	287			4	5
Arthrofibrosis	1	1	1				
Arthropathy	601	70	193	152	408	2	3
Articular calcification	7	1	4	1	3		
Articular disc disorder	1			1	1		
Asymmetric thigh fold	1			1	1		
Autoimmune arthritis	26	11	26				
Autoimmune myositis	39	26	39				
Axial spondyloarthritis	3	1	3				
Axillary mass	1498	126	379	344	1119		
Back disorder	95	11	24	14	71		3
Back pain	19445	1351	5000	4297	14445	20	53
Bone atrophy	1	1	1				
Bone cyst	6	1	2	2	4	1	1
Bone deformity	6	1	1	1	5		
Bone demineralisation	1				1		
Bone development abnormal	1				1		
Bone disorder	84	8	19	14	65		2
Bone erosion	1	1	1				

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bone formation increased	1			1	1		
Bone hypertrophy	1				1		
Bone infarction	2		2				
Bone lesion	9	1	2	3	7		
Bone loss	3		2		1		
Bone pain	4671	256	944	1095	3727	2	8
Bone swelling	129	14	42	17	87		
Bursa disorder	22	2	4	7	18		
Bursal fluid accumulation	15	2	5	4	10		
Bursal haematoma	3		2		1		
Bursitis	704	81	225	212	479		2
Calcification of muscle	2	1	1	1	1		
Callus formation delayed	1				1		
Camptocormia	3		1		2		
Carpal collapse	1		1				
Cartilage atrophy	1			1	1		
Cartilage hypertrophy	1		1				
Cervical spinal stenosis	16	4	16			1	1
Chest wall cyst	1		1				
Chest wall haematoma	3	1	3				
Chest wall mass	7	1	2	3	5		
Chondritis	7	1	2	1	5		
Chondrocalcinosis	24		13	6	11		
Chondrocalcinosis pyrophosphate	20	3	12	1	8		1
Chondromalacia	1		1				
Chondropathy	15	1	6	3	9		
Chronic recurrent multifocal osteomyelitis	1			1	1		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Clubbing	3		1	2	2		
Coccydynia	84	8	18	22	66		1
Collagen disorder	37	7	18	8	19		
Compartment syndrome	14	6	14				
Connective tissue disorder	161	13	26	6	135		
Connective tissue inflammation	11	4	6	2	5		
Costochondritis	505	77	204	184	301		
CREST syndrome	1		1				
Crystal arthropathy	14	3	9	1	5		
Dactylitis	21	4	9	5	12		
Decreased nasolabial fold	7	1	4		3		
Deformity thorax	4		2	1	2		
Degenerative bone disease	7			3	7		
Drooping shoulder syndrome	5	2	3	1	2		
Dupuytren's contracture	16	8	16				
Dysponesis	1				1		
Eagle's syndrome	1				1		
Elbow deformity	1				1		
Enostosis	1			1	1		
Enteropathic spondylitis	1				1		
Enthesopathy	62	19	35	15	27		
Eosinophilic fasciitis	9	8	9				
Epiphyses premature fusion	1		1				
Exostosis	22		7	5	15		1
Extremity contracture	27		7	3	20		
Facet joint syndrome	5		1	1	4		
Facial asymmetry	151	20	90	12	61		1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Facial myokymia	5	4	5				
Fasciitis	32	7	13	8	19		
Femoroacetabular impingement	1			1	1		
Fibromyalgia	756	131	340	177	416	1	3
Finger deformity	50	5	16	10	34		
Fistula	15	4	10	3	5	1	1
Fistula discharge	2	1	1		1		
Flank pain	621	54	186	157	435		
Fluctuance	3			2	3		
Focal myositis	2				2		
Foot deformity	52	9	20	9	32		2
Fracture pain	6		2	2	4		
Gouty arthritis	20	4	9	6	11		
Gouty tophus	3	1	2		1		
Greater trochanteric pain syndrome	29	2	14	6	15		
Groin pain	869	70	277	211	592		3
Growing pains	10	1	2		8		
Growth accelerated	1	1	1				
Growth disorder	3		1	1	2		
Growth failure	1		1				
Growth retardation	1	1	1				
Haemarthrosis	43	7	43			1	1
Haematoma muscle	50	4	23	8	27		
Haemophilic arthropathy	2	1	2				
Hand deformity	40	9	20	8	20		1
Head deformity	5		3	1	2		
Hip deformity	2		1		1		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hydroxyapatite crystal deposition disease	1			1	1		
Hypercreatinaemia	1				1		
Hypermobility syndrome	10	2	5	1	5		
Hypotonia neonatal	3	1	3				
Idiopathic inflammatory myopathy	6	1	6				
Immobilisation syndrome	14	1	10	1	4		
Immune-mediated arthritis	4	1	4				
Immune-mediated myositis	10	4	10				
Immunoglobulin G4 related disease	8	2	8				
Inclusion body myositis	3	1	3				
Infrapatellar fat pad inflammation	2			2	2		
Inguinal mass	16	4	12	2	4		
Interspinous osteoarthritis	1		1				
Intervertebral disc annular tear	4		2		2		
Intervertebral disc compression	5		2	3	3		
Intervertebral disc degeneration	43	3	13	13	30		1
Intervertebral disc disorder	72	10	23	35	49		
Intervertebral disc displacement	1		1				
Intervertebral disc protrusion	216	26	70	72	146	3	6
Intervertebral disc space narrowing	8	1	3	2	5		
Jaw clicking	23	1	6	5	17		
Jaw cyst	5			3	5		
Jaw disorder	95	4	22	15	73		1
Joint adhesion	2			1	2		
Joint ankylosis	63	5	14	18	49		
Joint contracture	22	5	8	4	14		
Joint deposit	3	1	3				

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Joint destruction	5	2	5				
Joint effusion	252	32	100	61	152		
Joint hyperextension	11	2	8		3	1	1
Joint instability	34	4	13	7	21		
Joint laxity	6		4		2		
Joint lock	151	21	69	16	82		
Joint microhaemorrhage	2		2				
Joint noise	148	20	65	36	83	1	3
Joint range of motion decreased	1954	204	748	217	1206	2	7
Joint space narrowing	3			1	3		
Joint stiffness	1464	170	545	288	919	2	5
Joint swelling	4150	382	1375	908	2775	4	12
Joint vibration	13	2	4	7	9		
Joint warmth	100	13	41	10	59		1
Juvenile idiopathic arthritis	29	13	29			1	4
Juvenile polymyositis	1	1	1				
Juvenile psoriatic arthritis	1	1	1				
Knee deformity	5			2	5		
Kyphoscoliosis	2		1		1		
Kyphosis	6		3	1	3		
Ligament disorder	12	4	7		5	1	1
Ligamentitis	11	1	5	5	6		
Ligament laxity	3	1	1		2		
Ligament pain	36	2	8	14	28		
Limb deformity	22	2	7	3	15		
Limb discomfort	23851	653	2500	10887	21351	16	55
Limb mass	294	34	102	44	192		2

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Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Locomotive syndrome	3		2	1	1		
Loose body in joint	3		1		2		
Lordosis	6		3		3		
Lumbar spinal stenosis	15	1	5	5	10		
Lupus-like syndrome	23	7	23				
Lupus myositis	1		1				
Mandibular mass	5		2	1	3		
Mastication disorder	158	16	55	28	103		1
Masticatory pain	7			2	7		
Medial tibial stress syndrome	15	4	9	3	6		
Meniscal degeneration	1			1	1		
Metatarsalgia	8	1	3	3	5		
Mitochondrial myopathy acquired	1		1				
Mixed connective tissue disease	21	11	21				1
Mobility decreased	4019	396	1292	756	2727	4	11
Morphoea	23	3	7	9	16		
Mucoid degeneration of the anterior cruciate ligament	1				1		
Muscle atrophy	273	65	129	72	144		
Muscle contracture	257	19	63	53	194		1
Muscle discomfort	325	14	41	123	284	1	2
Muscle disorder	264	27	81	61	183	1	1
Muscle fatigue	930	79	403	127	527		7
Muscle fibrosis	2			2	2		
Muscle haemorrhage	22	3	22				
Muscle hypertrophy	8	3	8				
Muscle hypoxia	3	2	3				
Muscle infarction	2	1	2				

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Muscle mass	27	1	8	6	19		1
Muscle necrosis	8	1	8				
Muscle oedema	35	5	13	6	22		
Muscle rigidity	393	39	149	51	244	2	4
Muscle spasms	10357	789	3170	2361	7187	5	20
Muscle swelling	227	17	69	43	158		
Muscle tightness	1728	100	391	427	1337	1	3
Muscle twitching	3309	344	966	999	2343	1	3
Muscular weakness	10735	1274	4255	2286	6480	12	34
Musculoskeletal chest pain	1889	181	608	447	1281	1	5
Musculoskeletal deformity	1		1				
Musculoskeletal discomfort	1506	95	332	394	1174	2	3
Musculoskeletal disorder	524	42	189	59	335	2	6
Musculoskeletal pain	5149	305	959	690	4190	1	5
Musculoskeletal stiffness	8639	626	2566	1677	6073	7	28
Myalgia	177523	4331	18559	39252	158964	120	376
Myalgia intercostal	40	1	10	6	30		
Myofascial pain syndrome	37	4	16	10	21		
Myofascial spasm	3		1		2		
Myofascitis	9	1	4	1	5		
Myoglobinaemia	1	1	1				
Myokymia	73	12	31	19	42		
Myopathy	88	17	48	19	40		
Myopathy toxic	1	1	1				
Myosclerosis	45	23	45				1
Myositis	572	110	256	139	316	2	4
Myositis-like syndrome	1			1	1		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neck deformity	10	2	3	1	7		
Neck mass	316	35	93	46	223		1
Neck pain	13047	907	3658	2511	9389	9	28
Necrotising myositis	8	7	8				
Neuropathic arthropathy	3	2	3				
Neuropathic muscular atrophy	7	3	7				
Nodal osteoarthritis	13		1	3	12		
Nose deformity	6	1	2		4		
Nuchal rigidity	300	16	68	78	232	2	2
Oligoarthritis	26	9	21		5		
Osteitis	95	8	26	32	69		
Osteitis condensans	1		1				
Osteoarthritis	552	90	203	154	349	4	9
Osteoarthropathy	9	1	1	1	8		
Osteochondritis	5				5		
Osteochondrosis	7	4	6	1	1		
Osteolysis	10	3	4	4	6		
Osteo-meningeal breaches	1	1	1				
Osteonecrosis	24	11	24			2	2
Osteonecrosis of jaw	4	2	4				
Osteopenia	22	2	9	3	13	1	1
Osteoporosis	55	6	19	17	36	3	4
Osteoporotic fracture	5	1	5				
Osteosclerosis	3	1	1	2	2		
Pain in extremity	92942	4490	18403	20439	74539	92	419
Pain in jaw	2247	145	632	491	1615		7
Palindromic rheumatism	22	12	22			1	1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Palmar fasciitis	1	1	1				
Paraneoplastic arthritis	2		2				
Patellofemoral pain syndrome	4	2	3	1	1		
Pathological fracture	6	3	4	1	2		
Pelvic misalignment	3		1	2	2		
Periarthritis	802	185	440	186	362	1	3
Periarticular disorder	1		1				
Periostitis	16	2	2	10	14		
Plantar fascial fibromatosis	7	1	3	3	4		
Plantar fasciitis	82	8	30	20	52		
Plica syndrome	2			1	2		
Polyarthritis	351	145	351				
Polychondritis	10	2	10				
Polymyalgia rheumatica	1014	429	1014			2	4
Polymyositis	39	11	39			1	1
Posterior tibial tendon dysfunction	2		1	1	1		
Posture abnormal	54	5	19	12	35		
Pseudothrombophlebitis	1		1				
Psoriatic arthropathy	207	99	207			28	42
Pubic pain	18	2	5	5	13		
Purple glove syndrome	1		1				
Resorption bone increased	2	1	1	1	1		
Retrognathia	1		1				
Reynold's syndrome	6	3	6				
Rhabdomyolysis	294	78	294				
Rheumatic disorder	518	68	176	214	342		
Rheumatic fever	16	7	16				

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Rheumatoid arthritis	1364	539	1364			115	194
Rheumatoid bursitis	1		1				
Rheumatoid nodule	9	2	5	3	4		
Rib deformity	1				1		
Rotator cuff injury of hip	1				1		
Rotator cuff syndrome	293	59	137	74	156	2	6
Sacral pain	109	6	22	27	87		1
Sacroiliac joint dysfunction	15	1	3	8	12		
Sacroiliitis	32	3	17	7	15		
SAPHO syndrome	5	1	5				
Sarcopenia	6	1	2	3	4		
Scapular dyskinesis	3	1	1	1	2		
Sclerodactylia	3	1	3				
Scleroderma	39	23	39			1	1
Scoliosis	27	5	11	7	16		
Seronegative arthritis	51	22	51				
Shoulder deformity	9	2	4	3	5		
Shoulder girdle pain	3			3	3		
Sinus tarsi syndrome	1				1		
Sjogren's syndrome	149	75	149				
SLE arthritis	6		6				
Slipping rib syndrome	6		2	2	4		
Snapping hip syndrome	2			1	2		
Soft tissue atrophy	3		1	2	2		
Soft tissue disorder	19	3	9	6	10		
Soft tissue haemorrhage	4	1	2		2		
Soft tissue mass	11	2	6	3	5		

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System Organ Class

Musculoskeletal and connective tissue disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Soft tissue necrosis	2	1	2				
Soft tissue swelling	124	8	21	8	103		
Somatic dysfunction	3		2	1	1		
Spinal deformity	15	2	6	4	9		
Spinal disorder	83	12	41	16	42	2	3
Spinal flattening	2			1	2		
Spinal fusion acquired	1		1				
Spinal instability	9	2	3	2	6		
Spinal osteoarthritis	132	17	47	41	85		
Spinal pain	1253	135	392	301	861		3
Spinal retrolisthesis	1				1		
Spinal stenosis	40	8	22	4	18		1
Spinal synovial cyst	1		1				
Spondylitis	105	17	54	25	51	1	1
Spondyloarthropathy	12	4	8	2	4		
Spondylolisthesis	7	3	5	1	2		
Spondylolysis	3	1	1		2		
Stenocephaly	1		1				
Still's disease	83	36	83				1
Sympathetic posterior cervical syndrome	3	2	3				
Symphysiolysis	6		1	1	5		
Synovial cyst	264	14	72	77	192	1	2
Synovial disorder	8	1	3	3	5		
Synovitis	129	16	56	37	73	2	2
Systemic lupus erythematosus	315	139	315			9	13
Systemic scleroderma	12	7	12				
Temporomandibular joint syndrome	135	14	41	25	94		1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tendinous contracture	4		1	3	3		
Tendon calcification	11	2	5	4	6		
Tendon discomfort	54	5	7	23	47		
Tendon disorder	191	43	78	52	113		
Tendonitis	634	91	215	181	419	2	5
Tendon laxity	2	1	1	1	1		
Tendon pain	389	37	107	122	282	3	4
Tendon sheath disorder	17			12	17		
Tenosynovitis	156	26	62	40	94		
Tenosynovitis stenosans	15	1	5	6	10		
Thoracic spinal stenosis	2		2				
Toe walking	1				1		
Torticollis	221	7	40	49	181		
Trendelenburg's symptom	2	1	2				
Trigger finger	117	20	43	14	74	2	2
Trismus	298	26	102	53	196		
Undifferentiated connective tissue disease	3		2	1	1		
Undifferentiated spondyloarthritis	2	1	2				
Vertebral end plate inflammation	2		1	1	1		
Vertebral foraminal stenosis	5	1	2	3	3		
Vertebral lesion	4		3	1	1		
Vertebral osteophyte	5			3	5		
Vertebral wedging	2		1		1		
Weight bearing difficulty	551	72	128	322	423	2	2
Winged scapula	20	5	11	6	9		
Wrist deformity	3		2	1	1		
Total:	539299	26600	98309	120908	440990	645	1823

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
5q minus syndrome	1		1				
Abdominal neoplasm	4		2	1	2		
Acinic cell carcinoma of salivary gland	1	1	1				
Acoustic neuroma	15	5	15				
Acrochordon	9	2	5	2	4		
Acute leukaemia	28	9	28				
Acute lymphocytic leukaemia	19	8	19				
Acute megakaryocytic leukaemia	1		1				
Acute monocytic leukaemia	1		1				
Acute myeloid leukaemia	45	16	45				
Acute myeloid leukaemia recurrent	7	4	7				
Acute myelomonocytic leukaemia	1	1	1				
Acute promyelocytic leukaemia	2	1	2				
Adenocarcinoma	7	6	7				
Adenocarcinoma gastric	2	1	2				
Adenocarcinoma metastatic	2		2				
Adenocarcinoma of colon	3	2	3				
Adenocarcinoma pancreas	2	1	2				
Adenolymphoma	1			1	1		
Adenoma benign	6	1	2		4		
Adrenal adenoma	9		2	1	7		
Adrenal gland cancer	3	3	3				
Adrenal neoplasm	2	2	2				
Adult T-cell lymphoma/leukaemia	2	2	2				
Anal cancer	1	1	1				
Anaplastic thyroid cancer	2	1	2				
Angiocentric lymphoma	3	3	3				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Angiofibroma	1	1	1				
Angioimmunoblastic T-cell lymphoma	5	2	5				
Angioimmunoblastic T-cell lymphoma recurrent	1		1				
Angiolipoma	1		1				
Angiomyolipoma	5	2	5				
Angiosarcoma	1	1	1				
Anogenital warts	19	2	6	6	13		
Appendix cancer	1	1	1				
Astrocytoma	1		1				
Basal cell carcinoma	28	16	28			1	1
Basosquamous carcinoma	1	1	1				
B-cell lymphoma	21	8	21			1	1
B-cell small lymphocytic lymphoma	1		1				
B-cell type acute leukaemia	5	2	5				
Benign bone neoplasm	1	1	1				
Benign breast neoplasm	13	4	7	3	6	1	1
Benign gastrointestinal neoplasm	2	1	1	1	1		
Benign hepatic neoplasm	3	1	1		2		
Benign hydatidiform mole	12	6	12				
Benign lung neoplasm	1	1	1				
Benign lymph node neoplasm	3		1		2	1	1
Benign neoplasm	5		2	2	3		
Benign neoplasm of cervix uteri	1				1		
Benign neoplasm of skin	1			1	1		
Benign neoplasm of testis	1	1	1				
Benign neoplasm of thyroid gland	3	1	1	1	2	1	1
Benign ovarian tumour	2	1	2				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Benign salivary gland neoplasm	4	2	3	1	1		
Benign uterine neoplasm	1			1	1		
Bile duct cancer	5	1	5			1	1
Biliary adenoma	1	1	1				
Bladder adenocarcinoma stage unspecified	1		1				
Bladder cancer	15	11	15				
Bladder cancer recurrent	4	2	4			1	1
Bladder neoplasm	4	3	4				
Blast cell crisis	1		1				
Blast cell proliferation	1	1	1				
Blastic plasmacytoid dendritic cell neoplasia	1		1				
Bone cancer	7	5	7				
Bone cancer metastatic	2		2				
Bone neoplasm	26	2	8	5	18		
Borderline ovarian tumour	2	1	2				
Bowen's disease	2	1	2				
Brain cancer metastatic	3	1	3				
Brain neoplasm	49	20	49			4	4
Brain neoplasm benign	1	1	1				
Brain neoplasm malignant	2	1	2				
Breast adenoma	2	1	1		1		
Breast cancer	169	81	169				2
Breast cancer female	29	24	29			2	3
Breast cancer in situ	1		1				
Breast cancer male	4	2	4				
Breast cancer metastatic	17	9	17				
Breast cancer recurrent	16	10	16				

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System Organ Class

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Breast cancer stage I	1		1				
Breast cancer stage II	3		3				
Breast cancer stage III	3	1	3				
Breast cancer stage IV	3	1	3				
Breast neoplasm	11	6	9	1	2		
Bronchial carcinoma	9	6	9				
Bronchial neoplasm	1		1				
Burkitt's lymphoma	2	2	2				
Burkitt's lymphoma stage I	2		2				
Cancer fatigue	1			1	1		
Cancer pain	2	1	2			2	2
Carcinoid tumour	1		1				
Carcinoid tumour of the gastrointestinal tract	1		1				
Carcinoid tumour pulmonary	1		1				
Carcinoma in situ	1	1	1				
Cardiac neoplasm unspecified	3	1	3				
Cardiac valve fibroelastoma	4	1	4				
Cartilage neoplasm	1				1		
Castleman's disease	14	6	14				
Central nervous system lymphoma	4	1	4				
Cerebral haemangioma	2		2				
Cervix carcinoma	9	6	9				
Cervix carcinoma recurrent	1	1	1				
Cervix carcinoma stage 0	2	2	2				
Chloroma	1	1	1				
Cholangiocarcinoma	7	5	7				
Cholangiosarcoma	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cholesteatoma	1		1				
Chondroma	1		1				
Chondromatosis	2			2	2		
Chondrosarcoma	1	1	1				
Choroidal haemangioma	1				1		
Chronic leukaemia	4	1	4				
Chronic lymphocytic leukaemia	51	20	51				
Chronic lymphocytic leukaemia (in remission)	1			1	1		
Chronic lymphocytic leukaemia recurrent	2	1	2				
Chronic lymphocytic leukaemia stage 0	1		1				
Chronic lymphocytic leukaemia transformation	1	1	1				
Chronic myeloid leukaemia	13	8	13				
Chronic myeloid leukaemia recurrent	1		1				
Chronic myelomonocytic leukaemia	4	2	4				
Clear cell renal cell carcinoma	3	1	3				
Colon cancer	36	19	36				1
Colon cancer metastatic	3	1	3				
Colon cancer stage IV	2		2				
Colon neoplasm	7	3	7				
Colorectal adenocarcinoma	1		1				
Colorectal adenoma	2	1	1	1	1		
Colorectal cancer	3	2	3				
Cranial nerve neoplasm benign	1		1				
Craniopharyngioma	1	1	1				
Cutaneous lymphoma	6	3	6				
Cutaneous T-cell lymphoma	6	3	6				
Dermatofibrosarcoma protuberans	1	1	1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Desmoid tumour	2	1	2				
Diaphragm neoplasm	1	1	1				
Diffuse large B-cell lymphoma	21	11	21				
Diffuse large B-cell lymphoma stage IV	1	1	1				
Double hit lymphoma	1		1				
Ear neoplasm	3		1		2		
Elastofibroma	1				1		
Enchondromatosis	1	1	1				
Endocrine neoplasm malignant	1		1				
Endometrial adenocarcinoma	3	2	3				
Endometrial cancer	12	5	12				
Endometrial cancer metastatic	1	1	1				
Epithelioid mesothelioma	1	1	1				
Epithelioid sarcoma	2		2				
Epstein Barr virus positive mucocutaneous ulcer	1	1	1				
Erythroplasia	1		1				
Essential thrombocythaemia	15	5	15				
Ewing's sarcoma	1		1				
Extranodal marginal zone B-cell lymphoma (MALT type)	1	1	1				
Eye haemangioma	1			1	1		
Eyelid tumour	3			2	3		
Eye naevus	4	2	2	1	2		
Fallopian tube cancer	1		1				
Fallopian tube neoplasm	1		1				
Fibroadenoma of breast	20	7	11	6	9		
Fibroma	10	1	1	4	9		
Fibrous histiocytoma	5		2	2	3		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Focal nodular hyperplasia	3	1	1	2	2		
Follicle centre lymphoma, follicular grade I, II, III	1		1				
Follicular lymphoma	11	7	11				
Follicular lymphoma stage I	1		1				
Follicular lymphoma stage III	1	1	1				
Follicular lymphoma stage IV	1		1				
Gallbladder adenocarcinoma	1		1				
Gallbladder cancer	2	2	2				
Gallbladder cancer metastatic	1	1	1				
Gammopathy	3		1	1	2		
Ganglioneuroma	1		1				
Gastric adenoma	2	1	1	1	1		
Gastric cancer	10	5	10				
Gastric cancer recurrent	1		1				
Gastric cancer stage IV	2	2	2				
Gastric haemangioma	1		1				
Gastric neoplasm	1		1				
Gastrointestinal adenocarcinoma	1	1	1				
Gastrointestinal cancer metastatic	1	1	1				
Gastrointestinal carcinoma	10	7	10				
Gastrointestinal lymphoma	1	1	1				
Gastrointestinal neoplasm	2				2		
Gastrointestinal stromal tumour	2	1	2				
Gestational trophoblastic tumour	1	1	1				
Giant cell tumour of tendon sheath	1		1				
Glioblastoma	25	11	25				
Glioblastoma multiforme	2	2	2				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glioma	7	6	7				
Good syndrome	1		1				
Haemangioma	69	9	31	21	38	1	1
Haemangioma of bone	1				1		
Haemangioma of breast	2				2		
Haemangioma of liver	22	7	12	7	10		
Haemangioma of skin	33	2	8	7	25	1	1
Haemangioma of spleen	2		2				
Haemangioma rupture	1	1	1				
Haemangiopericytoma	1	1	1				
Haematological malignancy	2	1	2				
Haematopoietic neoplasm	2		2				
Hairy cell leukaemia	1		1				
Hepatic adenoma	3	2	3				
Hepatic cancer	18	7	18				
Hepatic cancer metastatic	2		2				
Hepatic cancer recurrent	1		1				
Hepatic neoplasm	10	4	10				
Hepatocellular carcinoma	9	6	9				
HER2 positive breast cancer	2	1	2				
High-grade B-cell lymphoma	2	2	2				
High grade B-cell lymphoma Burkitt-like lymphoma	1	1	1				
Histiocytic necrotising lymphadenitis	15	6	10	1	5		
Histiocytosis	4	1	4				
Hodgkin's disease	24	10	24				
Hodgkin's disease mixed cellularity stage unspecified	2	2	2				
Hodgkin's disease recurrent	1	1	1				

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hormone receptor positive breast cancer	1		1				
Hormone receptor positive HER2 negative breast cancer	1	1	1				
Huerthle cell carcinoma	1	1	1				
Hypergammaglobulinaemia benign monoclonal	5	2	3		2		
Infected neoplasm	1			1	1		
Inflammatory carcinoma of the breast	6	3	6				
Inflammatory pseudotumour	1			1	1		
Intestinal adenocarcinoma	1	1	1				
Intra-abdominal haemangioma	2	1	2				
Intraductal papillary mucinous neoplasm	3	2	2	1	1		
Intraductal papilloma of breast	1			1	1		
Intraductal proliferative breast lesion	2		2				
Intravascular papillary endothelial hyperplasia	1	1	1				
Invasive breast carcinoma	1		1				
Invasive ductal breast carcinoma	16	8	16				
Invasive lobular breast carcinoma	2	2	2				
Joint neoplasm	1				1		
Kaposi's sarcoma	11	5	11				
Kaposi's sarcoma AIDS related	1		1				
Keratoacanthoma	2			1	2		
Langerhans' cell histiocytosis	4	3	4				
Large granular lymphocytosis	1	1	1				
Large intestine benign neoplasm	1				1		
Laryngeal cancer	1	1	1				
Laryngeal papilloma	1	1	1				
Leiomyoma	24	2	6	10	18		
Leiomyosarcoma	3		3			1	1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Leukaemia	57	25	57				
Leukaemia recurrent	5	2	5				
Leukaemic infiltration	1	1	1				
Leukaemic lymphoma	1		1				
Lip and/or oral cavity cancer	6	3	6				
Lip and/or oral cavity cancer recurrent	1		1				
Lip neoplasm malignant stage unspecified	2	2	2				
Lipoma	98	10	30	28	68		
Liposarcoma	3	1	3				
Liver carcinoma ruptured	1		1				
Lobular breast carcinoma in situ	2	2	2				
Lung adenocarcinoma	13	7	13				
Lung adenocarcinoma recurrent	1		1				
Lung adenocarcinoma stage IV	1	1	1				
Lung cancer metastatic	16	4	16				
Lung carcinoma cell type unspecified recurrent	3	1	3				
Lung carcinoma cell type unspecified stage 0	1		1				
Lung carcinoma cell type unspecified stage I	1		1				
Lung carcinoma cell type unspecified stage IV	2		2				
Lung neoplasm	5	2	5				
Lung neoplasm malignant	64	27	64			1	1
Lung squamous cell carcinoma stage I	1	1	1				
Lymphangioma	4		3	1	1		
Lymphatic system neoplasm	3		1	1	2		
Lymphocytic leukaemia	1	1	1				
Lymphoma	177	61	177			1	1
Lymphoproliferative disorder	6	2	6				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Malignant ascites	4	2	4				
Malignant lymphoid neoplasm	1		1				
Malignant melanoma	21	14	21				
Malignant neoplasm of eye	1		1				
Malignant neoplasm of renal pelvis	1		1				
Malignant neoplasm of unknown primary site	1	1	1				
Malignant neoplasm progression	18	5	18			1	1
Malignant nervous system neoplasm	2		2				
Malignant oligodendroglioma	1	1	1				
Malignant palate neoplasm	1	1	1				
Malignant peritoneal neoplasm	4	2	4			2	2
Malignant pleural effusion	3	1	3				
Malignant splenic neoplasm	1		1				
Mantle cell lymphoma	8	5	8				
Mantle cell lymphoma recurrent	2	1	2				
Marginal zone lymphoma	3	2	3				
Marrow hyperplasia	2		1		1		
Medulloblastoma	1		1				
Melanocytic naevus	47	4	10	16	37		
Melanoma recurrent	6	2	6				
Meningioma	39	17	39				
Meningioma benign	2	1	2				
Mesenteric neoplasm	1	1	1				
Mesothelioma	3		3				
Metastases to abdominal cavity	1	1	1				
Metastases to abdominal wall	1	1	1				
Metastases to adrenals	2	1	2				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Metastases to bone	15	9	15				
Metastases to breast	1		1				
Metastases to central nervous system	14	7	14				
Metastases to heart	1		1				
Metastases to liver	30	14	30				
Metastases to lung	18	8	18				
Metastases to lymph nodes	40	18	40				
Metastases to meninges	2		2				
Metastases to neck	1	1	1				
Metastases to peritoneum	6	4	6				
Metastases to pituitary gland	1		1				
Metastases to skin	3	2	3				
Metastases to spleen	2	1	2				
Metastases to the mediastinum	2	1	2				
Metastasis	23	11	23				
Metastatic bronchial carcinoma	2		2				
Metastatic lymphoma	3	1	3				
Metastatic malignant melanoma	5	3	5				
Metastatic neoplasm	15	7	15				
Metastatic renal cell carcinoma	1	1	1				
Monoclonal gammopathy	13	5	10		3		
Muscle neoplasm	1		1				
Myelodysplastic syndrome	54	23	54				
Myelofibrosis	6	2	6				
Myeloid leukaemia	4	2	4				
Myelolipoma	1			1	1		
Myeloproliferative neoplasm	7	1	7				

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Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Myxoma	1		1				
Naevus haemorrhage	1		1				
Naevus lipomatosus cutaneous superficialis	1				1		
Nasal cavity cancer	1	1	1				
Nasopharyngeal cancer	1	1	1				
Nasopharyngeal cancer metastatic	1	1	1				
Neoplasm	130	22	67	26	63	2	2
Neoplasm malignant	213	84	213				4
Neoplasm of orbit	1		1				
Neoplasm of thymus	1		1				
Neoplasm progression	94	20	72	4	22		1
Neoplasm recurrence	23	6	19		4		
Neoplasm skin	25	5	9	6	16		
Neoplasm swelling	4	1	2	1	2		
Nephroblastoma	1		1				
Neurilemmoma benign	2	1	2				
Neuroendocrine carcinoma	2	2	2				
Neuroendocrine carcinoma metastatic	1	1	1				
Neuroendocrine carcinoma of the skin	1		1				
Neuroendocrine tumour	4		3		1		
Neuroendocrine tumour of the lung metastatic	1	1	1				
Neuroendocrine tumour of the rectum	1	1	1				
Neurofibroma	2	2	2				
Neuroma	5	2	3	2	2		
Nodular fasciitis	1				1		
Nodular lymphocyte predominant Hodgkin lymphoma	2	1	2				
Nodular melanoma	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Non-Hodgkin's lymphoma	29	11	29				
Non-Hodgkin's lymphoma recurrent	3	1	3				
Non-Hodgkin's lymphoma stage IV	2	2	2				
Non-small cell lung cancer	1	1	1				
Ocular lymphoma	1	1	1				
Oesophageal adenocarcinoma	1	1	1				
Oesophageal cancer metastatic	2		2				
Oesophageal carcinoma	6	3	6				
Oesophageal neoplasm	1	1	1				
Oesophageal squamous cell carcinoma	1		1				
Oligodendroglioma	2	1	2				
Oncocytoma	1				1		
Oncologic complication	2		1		1		
Optic glioma	1		1				
Oral haemangioma	1			1	1		
Oral neoplasm	1		1				
Oral papilloma	1		1				
Oropharyngeal neoplasm benign	1				1		
Osteochondroma	1	1	1				
Osteoma	1		1				
Osteosarcoma	1	1	1				
Ovarian cancer	14	8	14				
Ovarian cancer recurrent	1	1	1				
Ovarian cancer stage III	1		1				
Ovarian cancer stage IV	1		1				
Ovarian dysgerminoma stage unspecified	2	2	2				
Ovarian epithelial cancer	1		1				

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System Organ Class

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ovarian germ cell cancer	1	1	1				
Ovarian germ cell teratoma benign	2	1	1		1		
Ovarian granulosa cell tumour	1		1				
Ovarian neoplasm	4	1	4				
Paget's disease of nipple						1	1
Paget's disease of the vulva	1	1	1				
Pancreatic carcinoma	32	15	32				
Pancreatic carcinoma metastatic	4	1	4				
Pancreatic neoplasm	4		3	1	1		1
Papillary cystadenoma lymphomatosum	5	3	3	2	2		
Papillary thyroid cancer	7	6	7				
Papilloma	4	1	2	1	2		
Paraganglion neoplasm	1		1				
Paraneoplastic syndrome	6	1	6				
Paraproteinaemia	1				1		
Parathyroid tumour	1		1				
Parathyroid tumour benign	3	2	3				
Pelvic neoplasm	2	1	2				
Penile wart	1		1				
Pericardial lipoma	1		1				
Pericardial mesothelioma malignant	1	1	1				
Peritoneal neoplasm	1		1				
Phaeochromocytoma	4	1	4				
Pharyngeal neoplasm	7	2	7				
Phyllodes tumour	1			1	1		
Pituitary tumour	3	2	3				
Pituitary tumour benign	14	3	7	3	7		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Plasma cell leukaemia	2		2				
Plasma cell myeloma	40	21	40				
Plasma cell myeloma recurrent	4		4				
Plasma cell myeloma refractory	1		1				
Plasmacytoma	5	4	5				
Pleomorphic adenoma	3	2	2		1		
Pleomorphic malignant fibrous histiocytoma	1		1				
Pleural mesothelioma	1		1				
Pleural mesothelioma malignant	1		1				
Pleural neoplasm	3	2	2	1	1		
POEMS syndrome	5	2	5				
Polycythaemia vera	10	7	10				
Poorly differentiated thyroid carcinoma	1	1	1				
Post transplant lymphoproliferative disorder	2	2	2				
Primary gastrointestinal follicular lymphoma	1		1				
Primary mediastinal large B-cell lymphoma	2	2	2				
Primary myelofibrosis	1		1				
Prolactin-producing pituitary tumour	4	4	4				
Prostate cancer	45	23	45				
Prostate cancer metastatic	2	2	2				
Prostate cancer recurrent	2		2				
Prostatic adenoma	2		1		1		
Pyogenic granuloma	4		2		2		
Rectal adenocarcinoma	2	2	2				
Rectal cancer	4	1	4				
Rectal cancer metastatic	1	1	1				
Recurrent cancer	9	7	9				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Refractory anaemia with an excess of blasts	1	1	1				
Refractory cytopenia with unilineage dysplasia	1	1	1				
Renal cancer	14	3	14				2
Renal cancer metastatic	3	1	3				
Renal cancer recurrent	1	1	1				
Renal cell carcinoma	2	1	2				
Renal hamartoma	2	2	2				
Renal neoplasm	10	2	8	1	2		
Retroperitoneal neoplasm	1	1	1				
Rhabdoid tumour	1	1	1				
Rhabdomyosarcoma	1		1				
Richter's syndrome	1		1				
Rosai-Dorfman syndrome	3	2	3				
Salivary gland adenoma	3		2	1	1		
Salivary gland cancer	1	1	1				
Salivary gland neoplasm	9	5	8	1	1		
Sarcoma	3	1	3				
Sarcoma of skin	1	1	1				
Schwannoma	5		3	1	2		
Seborrhoeic keratosis	9	2	2	3	7		
Second primary malignancy	4	1	4				
Seminoma	1	1	1				
Skin cancer	17	10	17			2	2
Skin papilloma	89	7	20	30	69	2	2
Skin squamous cell carcinoma metastatic	1	1	1				
Small cell carcinoma	1	1	1				
Small cell lung cancer	7	5	7				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Small cell lung cancer metastatic	1	1	1				
Small intestine carcinoma	1		1				
Soft tissue neoplasm	2	1	1	1	1		
Soft tissue sarcoma	2	1	2				
Solitary fibrous tumour	1		1				
Spinal meningioma benign	2	1	2				
Spindle cell sarcoma	1		1				
Squamous cell carcinoma	18	10	18				
Squamous cell carcinoma of skin	6	3	6			1	2
Squamous cell carcinoma of the oral cavity	1		1				
Squamous cell carcinoma of the tongue	1		1				
Systemic mastocytosis	2	2	2				
T-cell lymphoma	5	1	5				
T-cell lymphoma recurrent	1	1	1				
TEMPI syndrome	1		1				
Teratoma	1			1	1		
Testicular neoplasm	2	1	2				
Testis cancer	14	10	14				
Throat cancer	2	1	2				
Thymoma	6	2	6				
Thyroid adenoma	5	1	1	4	4		
Thyroid cancer	12	5	12				
Thyroid cancer recurrent	1	1	1				
Thyroid neoplasm	5	3	5				
Tonsil cancer	4	1	4				
Transitional cell carcinoma	1		1				
Triple negative breast cancer	5	2	5				

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Triple positive breast cancer	1		1				
Tumour associated fever	1		1				
Tumour flare	1	1	1				
Tumour haemorrhage	6	2	6				
Tumour inflammation	2		1		1		
Tumour necrosis	1	1	1				
Tumour pain	7	1	7				
Tumour perforation	2	1	2				
Tumour pseudoprogression	1		1				
Tumour rupture	3		3				
Tumour thrombosis	2		2				
Undifferentiated nasopharyngeal carcinoma	1	1	1				
Urinary tract neoplasm	2	1	2				
Uterine cancer	5	2	5			1	1
Uterine leiomyoma	98	18	44	24	54	2	2
Uterine neoplasm	1		1				
Uveal melanoma	1	1	1				
Vaginal cancer recurrent	1	1	1				
Vaginal cancer stage 0	1	1	1				
Vulval cancer	1	1	1				1
Vulvovaginal warts	1				1		
Waldenstrom's macroglobulinaemia	7	4	7				
Waldenstrom's macroglobulinaemia stage III	1		1				
Xanthogranuloma	1				1		
Yolk sac tumour site unspecified	1		1				
Total:	3711	1391	3092	266	619	34	48

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acalculia	2	2	2				
Accessory nerve disorder	2	1	1		1		
Acquired syringomyelia	2	1	2				
Acrodynia	1				1		
Action tremor	8	1	3	2	5		
Acute disseminated encephalomyelitis	151	40	151				
Acute flaccid myelitis	3	3	3				
Acute motor axonal neuropathy	13	5	13			1	1
Acute motor-sensory axonal neuropathy	9	4	9				
Acute polyneuropathy	75	35	75				
Adrenergic syndrome	2	1	1		1		
Advanced sleep phase	1				1		
Ageusia	4230	193	866	892	3364	5	27
Agitation neonatal	6	1	2	4	4		
Agnosia	12	3	7		5		
Agraphia	4	1	3	1	1		
Akathisia	42	4	13	8	29		
Akinesia	32	14	32				
Alcoholic seizure	1		1				
Alcohol induced persisting dementia	1		1				
Alexia	8	2	5		3		
Allodynia	172	21	61	43	111		
Altered pitch perception	3			1	3		
Altered state of consciousness	902	253	902			1	5
Amnesia	1674	202	751	339	923	2	6
Amnestic disorder	56	16	29	17	27	2	2
Amputation stump pain	2	1	1		1		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Amyloid related imaging abnormalities	1	1	1				
Amyotrophic lateral sclerosis	59	41	59			1	1
Anaesthesia	282	6	40	30	242		
Anaesthesia dolorosa	2	1	2				
Anosmia	3344	149	656	726	2688	2	23
Anosognosia	7	1	4	1	3		
Anterograde amnesia	17	4	17				
Anticholinergic syndrome	2		2				
Apallic syndrome	12	1	12				
Aphasia	1997	310	1040	438	957	1	8
Apraxia	67	11	39	7	28		1
Aqueductal stenosis	3	1	3				
Arachnoid cyst	18	4	9	3	9		
Arachnoiditis	6	4	6				
Areflexia	145	25	89	21	56		
Asterixis	14	3	14				
Ataxia	383	78	243	48	140	1	2
Athetosis	1				1		
Atonic seizures	35	6	22	6	13		
Auditory nerve disorder	11	2	6	1	5	1	1
Aura	185	21	64	40	121		2
Autoimmune demyelinating disease	6		6				
Autoimmune encephalopathy	8	3	8				
Autoimmune neuropathy	15	5	15				
Autonomic nervous system imbalance	225	41	121	52	104		
Autonomic neuropathy	33	12	33				
Autonomic seizure	4		4				

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Nervous system disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Axonal and demyelinating polyneuropathy	20	6	20				
Axonal neuropathy	31	9	21	3	10		
Balance disorder	4947	521	1874	1070	3073	5	23
Ballismus	11	4	8	1	3		
Band sensation	58	1	19	3	39		1
Basal ganglia haematoma	4	2	4				
Basal ganglia haemorrhage	34	9	34			1	1
Basal ganglia infarction	22	6	22				
Basal ganglia stroke	10	2	10				
Basilar artery aneurysm	1		1				
Basilar artery occlusion	13	3	13				
Basilar artery stenosis	5	3	5				
Basilar artery thrombosis	34	5	34				1
Basilar migraine	6		5	1	1		
Behavioural induced insufficient sleep syndrome	1			1	1		
Bell's palsy	3305	726	3305			8	15
Benign enlargement of the subarachnoid spaces	1		1				
Bickerstaff's encephalitis	11	2	11				
Blood brain barrier defect	4	1	4				
Brachial plexopathy	41	12	21	12	20		
Bradykinesia	206	31	96	23	110		1
Brain compression	16	4	16				
Brain hypoxia	20	3	20				
Brain injury	160	56	160				
Brain oedema	207	62	207				
Brain stem haematoma	1	1	1				
Brain stem haemorrhage	47	11	47				1

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Nervous system disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Brain stem infarction	108	34	108				
Brain stem ischaemia	13	3	13			1	1
Brain stem microhaemorrhage	1	1	1				
Brain stem stroke	26	8	26			1	2
Brain stem syndrome	24	9	24				
Brain stem thrombosis	7	2	7				
Brown-Sequard syndrome	8	2	8				
Brudzinski's sign	1				1		
Bulbar palsy	9	1	9				
Burning feet syndrome	32	7	16	10	16		
Burning sensation	6597	496	1720	1560	4877	3	15
Burning sensation mucosal	57	1	6	14	51		
Capsular warning syndrome	1		1				
Carotid aneurysm rupture	3	2	3				
Carotid arteriosclerosis	53	13	40		13	1	1
Carotid artery aneurysm	10	3	10				
Carotid artery disease	13	4	13				
Carotid artery dissection	68	32	68				
Carotid artery dolichoectasia	1			1	1		
Carotid artery occlusion	56	23	56			1	2
Carotid artery perforation	1		1				
Carotid artery stenosis	54	15	54			2	2
Carotid artery thrombosis	42	7	42				
Carpal tunnel syndrome	233	35	98	53	135	3	5
Cataplexy	16	6	16				
Cauda equina syndrome	15	5	15				
Cavernous sinus syndrome	2	2	2				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Central auditory processing disorder	1	1	1				
Central nervous system immune reconstitution inflammatory	1		1				
Central nervous system inflammation	50	23	50				
Central nervous system lesion	95	20	62	14	33		1
Central nervous system lupus	1	1	1				
Central nervous system necrosis	1		1				
Central nervous system vasculitis	26	7	26				
Central pain syndrome	33	7	12	5	21		
Cerebellar artery occlusion	2		2				
Cerebellar artery thrombosis	10	3	10				
Cerebellar ataxia	27	1	17	4	10		
Cerebellar atrophy	7	2	7			1	1
Cerebellar embolism	2	1	2				
Cerebellar haematoma	6	1	6				
Cerebellar haemorrhage	61	7	61				
Cerebellar infarction	141	42	141				
Cerebellar ischaemia	22	8	22				
Cerebellar stroke	64	14	64			1	1
Cerebellar syndrome	33	9	33				
Cerebellar tonsillar ectopia	1		1				
Cerebral amyloid angiopathy	18	5	18				
Cerebral arteriosclerosis	22	6	18		4		
Cerebral arteritis	1		1				
Cerebral artery embolism	75	19	75			1	1
Cerebral artery occlusion	62	18	62				
Cerebral artery perforation	2		2				
Cerebral artery stenosis	25	10	25				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cerebral artery thrombosis	57	12	57				
Cerebral atrophy	59	21	59				1
Cerebral calcification	3	1	1		2		1
Cerebral capillary telangiectasia	2		2				
Cerebral circulatory failure	2		2				
Cerebral congestion	15	1	10	3	5		
Cerebral cyst	8	2	4	1	4		
Cerebral disorder	144	20	74	16	70	1	2
Cerebral haematoma	93	20	93				
Cerebral haemorrhage	1160	305	1160			1	5
Cerebral haemorrhage foetal	4	2	4				
Cerebral haemorrhage neonatal	1	1	1			2	2
Cerebral hypoperfusion	5	3	5				
Cerebral infarction	1808	413	1808			3	6
Cerebral infarction foetal	1		1				
Cerebral ischaemia	276	75	276			1	4
Cerebral mass effect	6	1	6				
Cerebral microangiopathy	14	3	8	2	6		
Cerebral microembolism	1		1				
Cerebral microhaemorrhage	18	6	18				
Cerebral microinfarction	6	3	6				
Cerebral small vessel ischaemic disease	27	11	27				
Cerebral thrombosis	364	93	364			1	4
Cerebral vascular occlusion	3	1	3				
Cerebral vasoconstriction	11	2	11				
Cerebral vasodilatation	2		2				
Cerebral venous sinus thrombosis	516	165	516			2	3

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cerebral venous thrombosis	235	66	235			2	6
Cerebral ventricle dilatation	15	5	11	1	4	1	2
Cerebral ventricular rupture	14	3	14				
Cerebrosclerosis	1	1	1				
Cerebrospinal fluid circulation disorder	4		2	1	2		
Cerebrospinal fluid leakage	21	7	21				
Cerebrospinal fluid retention	1	1	1				
Cerebrovascular accident	4389	1331	4389			28	42
Cerebrovascular disorder	120	29	95	10	25	1	2
Cerebrovascular insufficiency	3	1	3				
Cerebrovascular stenosis	3	2	3				
Cervical cord compression	3	1	3				
Cervical radiculopathy	121	17	46	20	75		
Cervical spinal cord paralysis	3	2	3				
Cervicobrachial syndrome	158	19	60	35	98		
Cervicogenic headache	21	1	5	3	16		
Cervicogenic vertigo	6		1	2	5		
Change in seizure presentation	2		2				
Cholinergic syndrome	20	4	20				
Chorea	27	5	21	3	6		
Choreoathetosis	3			1	3		
Chronic inflammatory demyelinating polyradiculoneuropathy	68	39	68				
Chronic lymphocytic inflammation with pontine perivascular e	1		1				
Chronic paroxysmal hemicrania	1	1	1				
Circadian rhythm sleep disorder	35	5	11	6	24		1
Claude's syndrome	3	1	3				
Clinically isolated syndrome	18	6	18				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Clonic convulsion	44	13	44				2
Clonus	85	9	48	14	37		
Clumsiness	132	14	53	27	79		
Cluster headache	495	57	263	71	232	1	2
Cognitive disorder	1047	156	498	221	549	2	4
Cognitive linguistic deficit	6	2	3	1	3		
Cogwheel rigidity	4		1	1	3		
Cold dysaesthesia	3			2	3		
Cold-stimulus headache	58	10	29	5	29		
Coma	350	86	350			1	1
Coma hepatic	5		5				
Complex regional pain syndrome	106	26	61	24	45		1
Concentric sclerosis	2		2				
Consciousness fluctuating	21	4	21				
Conus medullaris syndrome	2	1	2				
Convulsion in childhood	3	2	3				
Convulsions local	22	3	22				
Convulsive threshold lowered	4	1	2	1	2		
Coordination abnormal	632	73	264	155	368	2	4
Cortical laminar necrosis	1		1				
Cramp-fasciculation syndrome	17	4	8	1	9		
Cranial nerve disorder	47	9	33	6	14		2
Cranial nerve palsies multiple	10	2	10				
Cranial nerve paralysis	29	3	29				
Cubital tunnel syndrome	19	3	9	5	10		
Cytotoxic lesions of corpus callosum	6	2	6				
Cytotoxic oedema	4	2	4			1	1

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Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Decerebrate posture	3		3				
Decorticate posture	2		2				
Decreased vibratory sense	34	4	15	13	19		
Delayed ischaemic neurological deficit	1		1				
Dementia	280	79	280			1	2
Dementia Alzheimer's type	63	18	63				
Dementia of the Alzheimer's type, with delirium	2	1	2				
Dementia with Lewy bodies	4	2	4				
Demyelinating polyneuropathy	68	30	68				
Demyelination	186	59	186				1
Depressed level of consciousness	1615	306	1615			2	6
Developmental coordination disorder	1	1	1				
Diabetic coma	9	3	9				
Diabetic hyperglycaemic coma							1
Diabetic hyperosmolar coma	3	1	3				
Diabetic ketoacidotic hyperglycaemic coma	1		1				
Diabetic neuropathy	9	1	3	3	6		1
Diplegia	218	84	218				1
Disturbance in attention	6441	599	1738	2233	4703	8	15
Dizziness	92642	5228	20465	25296	72177	188	429
Dizziness exertional	149	17	80	26	69		
Dizziness postural	1628	134	774	191	854	5	14
Dreamy state	15		4	3	11		
Drooling	132	20	67	16	65		1
Drop attacks	21	10	21				
Dropped head syndrome	6		4		2		
Drug withdrawal headache	1		1				

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dural arteriovenous fistula	6	3	6				
Dysaesthesia	1181	138	378	268	803	1	2
Dysarthria	1718	256	1067	203	651	1	15
Dyscalculia	4	1	2	2	2		
Dysdiadochokinesis	8	3	8				
Dysgeusia	6814	187	1015	1161	5799	1	9
Dysgraphia	108	16	46	30	62		
Dyskinesia	920	105	389	135	531		
Dyskinesia neonatal	1				1		
Dyslalia	108	12	87	4	21		
Dyslexia	24	3	9	5	15		
Dysmetria	18	3	18				1
Dyspraxia	37	5	22	3	15		
Dysprosody	1		1				
Dysstasia	1697	145	742	244	955	1	6
Dystonia	74	17	74				
Dystonic tremor	1	1	1				
Electric shock sensation	754	81	239	191	515		5
Embolic cerebellar infarction	7	4	7				
Embolic cerebral infarction	42	18	42				
Embolic stroke	137	29	137			2	2
Encephalitis autoimmune	66	29	66				
Encephalitis post immunisation	5		5				
Encephalomalacia	9	1	9				
Encephalopathy	155	44	155			1	2
Enlarged foetal cisterna magna	1	1	1				
Epidural lipomatosis	1				1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Epilepsy	1748	537	1748			4	10
Epileptic aura	20	2	9	7	11		
Epileptic encephalopathy	5	3	5				
Essential tremor	37	9	20	8	17		
Exaggerated startle response	6			3	6		
Exertional headache	29	4	14	5	15		
Extensor plantar response	24	3	15	4	9		
External compression headache	2		1	1	1		
Extrapyramidal disorder	32	7	21	7	11		
Facial nerve disorder	113	12	41	21	72		
Facial paralysis	5138	1417	5138			11	21
Facial paresis	1783	262	1066	275	717	6	9
Facial spasm	174	15	69	22	105		
Faciobrachial dystonic seizure	2	1	2				
Febrile convulsion	256	40	128	35	128	1	1
Febrile infection-related epilepsy syndrome	1		1				
Femoral nerve palsy	1			1	1		
Fine motor delay	3			3	3		
Fine motor skill dysfunction	181	27	80	46	101		
Focal dyscognitive seizures	19	8	19				
Foetal movement disorder	16	6	12	1	4		
Fontanelle bulging	1		1				
Fontanelle depressed	1	1	1				
Formication	864	66	201	211	663	1	1
Freezing phenomenon	44	4	17	8	27		
Frontotemporal dementia	2		2				
Fumbling	11		5	3	6		

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Nervous system disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gait spastic	5	2	3	2	2		
Gelastic seizure	1		1				
Generalised onset non-motor seizure	4		4				
Generalised tonic-clonic seizure	658	173	658			2	5
Geniculate ganglionitis	1				1		
Gerstmann's syndrome	1	1	1				
Glabellar reflex abnormal	1				1		
Glial scar	2	1	2				
Gliosis	14	2	6	5	8		
Glossopharyngeal nerve disorder	4	3	4				
Glossopharyngeal nerve paralysis	1	1	1				
Glossopharyngeal neuralgia	6	1	5	1	1		
Grimacing	2	1	2				
Gross motor delay	7	4	7				
Guillain-Barre syndrome	1559	519	1559			4	8
Haemorrhage intracranial	103	36	103				
Haemorrhagic cerebellar infarction	1	1	1				
Haemorrhagic cerebral infarction	25	7	25				
Haemorrhagic stroke	178	29	178				
Haemorrhagic transformation stroke	25	5	25				
Hand-eye coordination impaired	8		3	1	5		
Hashimoto's encephalopathy	2	1	2				
Headache	295929	9157	40417	68207	255512	293	909
Head discomfort	4589	256	1042	1056	3547	1	4
Head titubation	70	9	32	13	38		
Hemianaesthesia	82	39	82			1	2
Hemianopia	87	36	87				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hemianopia heteronymous	2		2				
Hemianopia homonymous	52	12	52				
Hemiapraxia	4		2		2		
Hemiasomatognosia	1		1				
Hemiataxia	16	4	16				
Hemidysaesthesia	42	11	42				
Hemihyperaesthesia	20	9	20				
Hemihypoaesthesia	255	115	255			1	3
Hemiparaesthesia	423	113	423			2	5
Hemiparesis	1527	490	1527			1	4
Hemiplegia	730	170	730			1	2
Hemiplegic migraine	82	21	58	13	24		
Hepatic encephalopathy	13	6	13				1
Hippocampal atrophy	7		2	1	5		
Hippocampal sclerosis	3	2	3				
Hoffmann's sign	5	1	2	2	3		
Homer's syndrome	26	9	26				
Hydrocephalus	64	20	64				
Hyperaesthesia	1526	107	356	421	1170	3	5
Hyperammonaemic encephalopathy	2	1	2				
Hypercapnic coma	4	1	4				
Hypergeusia	9		3	1	6		
Hyperintensity in brain deep nuclei	3		2	1	1		
Hyperkinesia	7	1	3		4		
Hyperpathia	7			2	7		
Hyperreflexia	63	12	39	14	24		
Hyperresponsive to stimuli	26	3	5	4	21		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypersomnia	1840	109	525	358	1315	2	6
Hypertensive cerebrovascular disease	1	1	1				
Hypertensive encephalopathy	18	2	18				
Hypertensive hydrocephalus	1	1	1				
Hypertonia	142	18	56	35	86		1
Hypoaesthesia	29444	2542	8710	6875	20734	20	67
Hypogeusia	303	4	39	89	264		
Hypoglossal nerve disorder	4	2	3	1	1		
Hypoglossal nerve paralysis	7	4	7				
Hypoglossal nerve paresis	2	1	2				
Hypoglycaemic coma	4	1	4				
Hypoglycaemic seizure	1		1				
Hypoglycaemic unconsciousness	5	1	5				
Hypokinesia	1730	249	640	337	1090		
Hypokinetic dysarthria	1		1				
Hyporeflexia	130	18	74	23	56		
Hyporesponsive to stimuli	50	4	35	4	15		
Hyposmia	208	3	29	69	179		
Hypotonia	1330	85	287	496	1043	2	2
Hypotonic-hyporesponsive episode	174	67	119	37	55	1	1
Hypoxic-ischaemic encephalopathy	47	16	47				
Idiopathic generalised epilepsy	4	3	4				
Idiopathic intracranial hypertension	64	22	64			4	4
IIIrd nerve disorder	17	4	16		1		
IIIrd nerve paralysis	90	25	90				
IIIrd nerve paresis	25	7	25				
Immune-mediated encephalitis	8	5	8				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Immune-mediated neurological disorder	4	2	4				
Immune-mediated neuropathy	10	6	10				
Inability to crawl	3		3				
Incoherent	113	11	62	12	51	1	1
Infant irritability	54	5	18	17	36		
Infant sedation	2	1	2				
Intellectual disability	23	9	23				
Intelligence increased	1				1		
Intensive care unit acquired weakness	1				1		
Intention tremor	11	3	8	1	3		
Intercostal neuralgia	64	9	17	23	47		2
Internal capsule infarction	6	2	6				
Intracranial aneurysm	97	32	97			1	1
Intracranial artery dissection	2		2				
Intracranial haematoma	7	3	7				
Intracranial hypotension	9	2	6		3		
Intracranial mass	11	5	10		1		
Intracranial pressure increased	154	58	154			1	1
Intraventricular haemorrhage	35	6	35				1
Irregular sleep phase	8		3	1	5		
Irregular sleep wake rhythm disorder	17	3	5	4	12		
Ischaemic cerebral infarction	144	33	144				
Ischaemic neuropathy	3	1	3				
Ischaemic stroke	1404	367	1404				7
IVth nerve disorder	4	1	3	1	1		
IVth nerve paralysis	32	4	32				
IVth nerve paresis	7	2	7				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Judgement impaired	11	2	2	1	9		
Juvenile myoclonic epilepsy	2		2				
Kernig's sign	1	1	1				
Lacunar infarction	93	21	93			1	3
Lacunar stroke	36	7	36				
Language disorder	363	63	152	133	211	4	5
Large fibre neuropathy	1	1	1				
Laryngeal tremor	1				1		
Lateral medullary syndrome	17	5	17				
Lateropulsion	5		3	1	2		1
Lennox-Gastaut syndrome	1		1				
Lethargy	9411	777	2799	1983	6612	7	30
Leukoencephalopathy	52	14	52				
Lewis-Sumner syndrome	2	1	2				
Lhermitte's sign	19	2	6	7	13		
Limbic encephalitis	30	8	30				
Locked-in syndrome	7	3	7				
Long thoracic nerve palsy	4			2	4		
Loss of consciousness	7652	1959	7651		1	15	51
Loss of proprioception	20	2	9	5	11		
Lower motor neurone lesion	9	1	5	3	4		
Lumbar radiculopathy	17	3	8	4	9		
Lumbosacral plexopathy	4	1	3	1	1		
Lumbosacral radiculopathy	17	3	9	3	8		
Lumbosacral radiculoplexus neuropathy	1	1	1				
Medication overuse headache	3		1		2		
Memory impairment	3044	303	906	1037	2138	4	12

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Meningeal disorder	28	4	12	7	16		
Meningeal thickening	3	1	2	1	1		
Meningism	86	7	34	12	52	2	2
Meningitis noninfective	2		1		1		
Meningoradiculitis	16	3	14	2	2		
Meningorrhagia	10	2	10				
Mental impairment	620	180	618	2	2	4	7
Meralgia paraesthetica	18	2	7	2	11		
Metabolic encephalopathy	9	3	9				
Micrographia	1		1				
Microsleep	3		1	1	2		
Microvascular cranial nerve palsy	3	2	3				
Migraine	12666	1013	4385	2746	8281	16	53
Migraine-triggered seizure	4	2	4				
Migraine with aura	784	94	329	173	455	1	4
Migraine without aura	45	8	25	7	20		
Miller Fisher syndrome	75	34	75				
Mononeuritis	33	8	22	6	11		
Mononeuropathy	28	4	19	7	9		
Mononeuropathy multiplex	24	10	20	2	4		
Monoparesis	537	111	337	71	200	2	7
Monoplegia	865	300	865			5	8
Morton's neuralgia	9		3	3	6		
Morvan syndrome	1		1				
Motor developmental delay	2		1		1		
Motor dysfunction	777	110	381	134	396		1
Motor neurone disease	24	10	24				

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Nervous system disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Movement disorder	2973	258	982	667	1991	1	7
Moyamoya disease	3	1	3				
Multifocal motor neuropathy	4	3	4				
Multiple sclerosis	572	246	572			18	22
Multiple sclerosis pseudo relapse	8	4	7		1		
Multiple sclerosis relapse	463	178	463			19	36
Multiple system atrophy	2		2				
Muscle contractions involuntary	738	76	214	214	524		1
Muscle spasticity	162	24	75	40	87	1	1
Muscle tension dysphonia	1			1	1		
Muscle tone disorder	9		2	3	7		
Myasthenia gravis	216	79	215	1	1		1
Myasthenia gravis crisis	16	2	16				
Myasthenic syndrome	22	7	22				
Myelin oligodendrocyte glycoprotein antibody-associated dis	9	7	9				
Myelitis transverse	248	89	248			1	1
Myelomalacia	3	2	3				
Myelopathy	52	23	52				
Myoclonic epilepsy	19	6	19				
Myoclonus	309	49	167	61	142		
Myotonia	5	1	3	1	2		
Myxoedema coma	1		1				
Narcolepsy	85	24	85				
Neonatal epileptic seizure	1	1	1				
Neonatal seizure	7	5	7				
Nerve compression	217	30	94	26	123	5	7
Nerve degeneration	7		3		4		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nervous system disorder	1121	181	539	266	582	2	3
Neuralgia	5243	590	1723	1490	3520	4	8
Neuralgic amyotrophy	391	147	262	63	129		1
Neuritic plaques	1			1	1		
Neuritis	407	70	161	115	246	2	3
Neuritis cranial	23	3	23				
Neurodegenerative disorder	10	7	10				
Neuroleptic malignant syndrome	10	4	10				
Neurological decompensation	21	5	18	2	3		
Neurological symptom	491	106	279	77	212	1	3
Neurologic neglect syndrome	43	11	31	2	12		
Neuromuscular blockade	7	1	1	4	6		
Neuromuscular pain	26	2	10	4	16		
Neuromyelitis optica spectrum disorder	65	22	65				
Neuromyopathy	35	12	35				
Neuromyotonia	2		1	1	1		
Neuronal neuropathy	4	1	4				
Neuropathy peripheral	1752	524	1751		1	4	16
Neuropsychiatric lupus	1		1				
Neurosarcoidosis	7	3	7				
Neurotoxicity	7	1	7				
Neurovascular conflict	1				1		
New daily persistent headache	52	12	30	11	22		
Non-24-hour sleep-wake disorder	4	1	1	2	3		
Noninfectious myelitis	3	1	3				
Noninfective encephalitis	67	33	67				
Normal pressure hydrocephalus	6	1	6				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Notalgia paraesthetica	3				3		
Numb chin syndrome	3		3				
Nystagmus	327	43	162	52	165		
Occipital neuralgia	126	12	49	26	77		
Oculocephalogyric reflex absent	1				1		
Oculofacial paralysis	8	2	8				
Olfactory dysfunction	3	2	2	1	1		
Olfactory nerve disorder	5			1	5		
On and off phenomenon	4			3	4		
Ophthalmic migraine	245	22	67	53	178	1	2
Ophthalmoplegic migraine	4			2	4		
Opisthotonus	9	2	9				
Optic neuritis	465	180	465			1	5
Optic perineuritis	3		3				
Oromandibular dystonia	8		3	3	5		
Orthostatic intolerance	90	17	41	15	49		
Orthostatic tremor	2				2		
Osmotic demyelination syndrome	1		1				
Pachymeningitis	11	4	11				
Palatal palsy	3	1	3				
Pancoast's syndrome	1		1				
Paraesthesia	44587	2989	10527	11990	34060	29	110
Paraesthesia mucosal	22	1	9	1	13		
Paralysis	1346	454	1346			3	7
Paralysis recurrent laryngeal nerve	10	5	10				
Paraneoplastic encephalomyelitis	2	2	2				
Paraparesis	112	32	112				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Paraplegia	72	29	72				
Paresis	447	85	249	74	198		1
Paresis cranial nerve	15	5	11		4		
Parkinsonian crisis	1		1				
Parkinsonian gait	7		1	4	6		
Parkinsonian rest tremor	5		1	1	4		
Parkinsonism	52	15	36	5	16		
Parkinson's disease	116	44	116			1	2
Parosmia	1956	97	382	458	1574		5
Paroxysmal sympathetic hyperactivity	2		2				
Partial seizures	149	41	149				
Partial seizures with secondary generalisation	11	3	11				
Patient elopement	14		5	2	9		
Perinatal stroke	2	1	2				
Periodic limb movement disorder	2	2	2				
Peripheral motor neuropathy	33	7	23	2	10	1	2
Peripheral nerve lesion	31	7	16	9	15		
Peripheral nerve palsy	16	3	7	4	9		
Peripheral nerve paresis	21	2	16	5	5		
Peripheral paralysis	33	7	33			1	2
Peripheral sensorimotor neuropathy	24	12	20	2	4		1
Peripheral sensory neuropathy	109	21	71	11	38		
Periventricular leukomalacia	4	2	4				
Peroneal nerve palsy	112	18	63	23	49		
Persistent genital arousal disorder	5	1	2	1	3		
Persistent postural-perceptual dizziness	34	5	22	7	12		
Petit mal epilepsy	155	35	155				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Phantom limb syndrome	29	3	8	7	21		
Phrenic nerve irritation	1			1	1		
Phrenic nerve paralysis	6	5	6				
Pineal gland cyst	5	2	5				
Piriformis syndrome	16	3	6	8	10		
Pleocytosis	41	11	27	2	14		
Pleurothotonus	1		1				
Polyneuropathy	516	249	515		1	1	2
Polyneuropathy chronic	4		2	1	2		
Polyneuropathy idiopathic progressive	2		2				
Polyneuropathy in malignant disease	1		1				
Poor sucking reflex	1		1				
Post-anoxic myoclonus	1	1	1				
Post cardiac arrest syndrome	3	1	3				
Posterior cortical atrophy	2	1	2				
Posterior interosseous syndrome	6	2	3	3	3		
Posterior reversible encephalopathy syndrome	13	3	13				1
Posthaemorrhagic hydrocephalus	1	1	1				
Post herpetic neuralgia	276	34	111	72	165	1	1
Postictal headache	1		1				
Postictal paralysis	15	3	15				
Postictal state	43	8	24	6	19		
Post polio syndrome	1		1				
Postresuscitation encephalopathy	1	1	1				
Post stroke epilepsy	2		2				
Post stroke seizure	1		1				
Post-traumatic epilepsy	3	2	3				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Post-traumatic neuralgia	2			1	2		
Postural tremor	5	2	5				
Precerebral artery occlusion	1		1				
Precerebral artery thrombosis	1		1				
Presbyastasis	2		1	1	1		
Presyncope	8427	522	2617	1619	5810	3	28
Primary cough headache	6		3		3		
Primary headache associated with sexual activity	16	5	13	1	3		
Primary progressive multiple sclerosis	1		1				
Prodromal Alzheimer's disease	1	1	1				
Progressive bulbar palsy	3	2	3				
Progressive multiple sclerosis	2	1	2				
Progressive supranuclear palsy	5	1	5				
Pronator teres syndrome	1	1	1				
Prosopagnosia	2		1	1	1		
Pseudobulbar palsy	1		1				
Pseudoparalysis	2	1	1	1	1		
Pseudoradicular syndrome	1	1	1				
Pseudostroke	5	3	5				
Psychogenic seizure	92	34	73	8	19		
Psychomotor disadaptation syndrome	2	2	2				
Psychomotor hyperactivity	207	18	72	34	135		
Psychomotor skills impaired	42	2	23	3	19		
Pudendal canal syndrome	15	6	9	3	6		
Putamen haemorrhage	32	2	32				
Pyramidal tract syndrome	17	9	17				
Quadrantanopia	20	5	20				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Quadriparesis	102	34	102				
Quadriplegia	60	12	60				
Radial nerve compression	1	1	1				
Radial nerve palsy	48	8	26	7	22		
Radicular pain	19	2	6	4	13		
Radiculitis brachial	60	8	37	10	23		
Radiculopathy	160	34	92	33	68		
Radiologically isolated syndrome	2	1	2				
Raymond-Cestan syndrome	1		1				
Reduced facial expression	68	5	27	6	41		
Reflexes abnormal	28	4	13	2	15		
Relapsing multiple sclerosis	9	3	9				
Relapsing-remitting multiple sclerosis	20	12	20				
Repetitive speech	9	2	6		3		
Resting tremor	22	2	9	5	13		
Restless arm syndrome	21	1	5	5	16		
Restless legs syndrome	611	53	185	159	426		
Retinal migraine	55	8	33	7	22		1
Retrograde amnesia	37	5	19	7	18		
Reversed hot-cold sensation	33	1	7	8	26		
Reversible cerebral vasoconstriction syndrome	18	8	18				
Reversible ischaemic neurological deficit	2		2				1
Right hemisphere deficit syndrome	2	2	2				
Ruptured cerebral aneurysm	50	13	50				
Sacral radiculopathy	1	1	1				
Sciatica	796	99	321	157	475	7	8
Sciatic nerve neuropathy	12	1	6	3	6		

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System Organ Class

Nervous system disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sciatic nerve palsy	6		3		3		
Secondary cerebellar degeneration	2		2				
Secondary progressive multiple sclerosis	3	1	3				
Sedation	155	13	43	26	112	2	3
Sedation complication	8	6	8				
Seizure	4484	1269	4484			14	26
Seizure anoxic	5	1	5				
Seizure cluster	8	1	8				
Seizure like phenomena	51	16	51				
Senile dementia	7	3	7				
Sensorimotor disorder	72	21	51	11	21		
Sensory disturbance	2226	229	794	542	1432	5	8
Sensory ganglionitis	1		1				
Sensory loss	977	140	464	176	513		5
Sensory overload	30	5	13	8	17		
Sensory processing disorder	13	3	8	4	5		
Serotonin deficiency	1			1	1		
Serotonin syndrome	6	2	6				
Sigmoid sinus thrombosis	1	1	1				
Simple partial seizures	6	2	6				
Sinus headache	540	42	254	38	286	1	4
Sleep deficit	165	9	47	36	118		
Sleep paralysis	79	5	20	19	59		
Slow response to stimuli	93	9	39	14	54		
Slow speech	135	20	71	13	64		
Small fibre neuropathy	137	43	77	32	60		
Somnolence	14376	568	2591	3350	11785	5	28

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Somnolence neonatal	1			1	1		
Spasmodic dysphonia	4	2	2		2		
Speech disorder	2221	264	1108	328	1113	2	7
Speech disorder developmental	16	3	6	2	10		
Spinal claudication	3	1	2		1		
Spinal cord compression	15	6	15			1	1
Spinal cord disorder	46	15	46				
Spinal cord haemorrhage	6	4	6				
Spinal cord herniation	1		1				
Spinal cord infarction	20	4	20				
Spinal cord ischaemia	14	6	14				
Spinal cord oedema	6	3	6				
Spinal epidural haematoma	3		3				
Spinal epidural haemorrhage	1		1				
Spinal meningeal cyst	5	2	5				
Spinal stroke	3	1	3				
Spinal subdural haemorrhage	1		1				
Spinal vascular disorder	3	1	3				
Spinocerebellar disorder	2	1	2				
Spondylitic myelopathy	1				1		
Status epilepticus	213	38	213				
Status migrainosus	22	5	15	7	7	3	3
Stiff leg syndrome	9		3	3	6		
Stiff person syndrome	8	3	8			1	1
Stroke in evolution	8	4	8				
Stupor	121	7	38	14	83		2
Subacute combined cord degeneration	1		1				

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System Organ Class

Nervous system disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Subacute inflammatory demyelinating polyneuropathy	3	2	3				
Subarachnoid haemorrhage	386	72	386				
Subdural hygroma	5	2	5				
Sudden onset of sleep	53	24	53				
Superficial siderosis of central nervous system	1				1		
Superior sagittal sinus thrombosis	39	10	39				1
Supranuclear palsy	1	1	1				
Supraorbital neuralgia	1			1	1		
Sydenham's chorea	1	1	1				
Sympathicotonia	9		1	3	8		
Sympathomimetic effect	1				1		
Synaesthesia	4	2	2	1	2		
Syncope	13947	4334	13946	1	1	29	124
Synkinesis	4	2	4				
Tardive dyskinesia	14	2	14				
Taste disorder	2609	98	455	634	2154		3
Temporal lobe epilepsy	13	5	13				
Tension headache	1353	121	555	212	798	3	13
Thalamic infarction	93	25	93			1	1
Thalamus haemorrhage	45	6	45			1	1
Thermoanaesthesia	4	1	2	1	2		
Thermohyperaesthesia	5		1	2	4		
Thermohypoaesthesia	16		10		6		
Thoracic outlet syndrome	25	3	9	8	16		
Thoracic spinal cord paralysis	1		1				
Thrombotic cerebral infarction	36	6	36				
Thrombotic stroke	36	6	36				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thunderclap headache	60	11	37	14	23		
Tinel's sign	6		2	2	4		
Tongue biting	101	10	65	12	36		
Tongue paralysis	68	28	68			1	1
Tonic clonic movements	86	23	86				
Tonic convulsion	113	26	112	1	1		
Tonic posturing	4		4				
Toxic encephalopathy	1		1				
Toxic neuropathy	2	1	2				
Transient aphasia	25	4	21		4		
Transient epileptic amnesia	1		1				
Transient global amnesia	121	20	73	12	48		1
Transient ischaemic attack	1635	426	1634	1	1	2	10
Transverse sinus stenosis	3		3				
Transverse sinus thrombosis	40	12	40				2
Tremor	11503	989	4221	2202	7282	14	40
Tremor neonatal	3	1	2	1	1		
Trigeminal nerve disorder	127	13	51	28	76		
Trigeminal nerve paresis	10	5	10				
Trigeminal neuralgia	858	125	317	214	541	2	3
Trigeminal neuritis	31	6	14	5	17		
Trigeminal neuropathy	2	1	1	1	1		
Trigeminal palsy	20	5	20				
Tumefactive multiple sclerosis	3	2	3				
Tunnel vision	129	26	128		1		
Typical aura without headache	22	3	15	1	7		
Uhthoff's phenomenon	7	1	3	2	4		

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System Organ Class

Nervous system disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ulnar nerve palsy	11	1	8		3		
Ulnar neuritis	15	3	15				
Ulnar tunnel syndrome	6	1	4	1	2		
Unresponsive to stimuli	445	90	445				
Upper motor neurone lesion	5	4	5				
Vagus nerve disorder	25	4	25			1	1
Vagus nerve paralysis	5	4	5				
Vascular cognitive impairment	1		1				
Vascular dementia	21	6	21				
Vascular encephalopathy	19	6	19				
Vascular headache	32	4	17	6	15		
Vascular parkinsonism	2	1	2				
Vasogenic cerebral oedema	5	2	5			1	1
Vertebral artery aneurysm	3		3				
Vertebral artery dissection	53	18	53			1	1
Vertebral artery occlusion	12	3	12				
Vertebral artery stenosis	6	2	6				
Vertebral artery thrombosis	12	3	12				
Vertebrobasilar dolichoectasia	1		1				
Vertebrobasilar insufficiency	8	4	6	1	2		
Vertebrobasilar stroke	18	3	18				
Vertigo CNS origin	8		4	1	4		1
Vestibular migraine	70	20	45	12	25	1	1
Vestibular nystagmus	2	1	1	1	1		
Vibration syndrome	9		4	4	5		
Vibratory sense increased	24	2	3	13	21		
VIIIth nerve lesion	4	2	3	1	1		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Visual agnosia	2	1	2				
Visual pathway disorder	10	2	3	2	7		
Visual perseveration	12		5	2	7		
Visuospatial deficit	4		2		2		
VIth nerve disorder	13	4	10	2	3		
VIth nerve paralysis	131	44	130	1	1	2	3
VIth nerve paresis	11	3	6	1	5		
Vocal cord paralysis	62	12	39	8	23		1
Vocal cord paresis	8		3	3	5		
Wallerian degeneration	1				1		
Wernicke's encephalopathy	1		1				
White matter lesion	64	14	40	9	24		
Writer's cramp	1		1				
Total:	696508	55315	205926	147308	490582	932	2619

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal cord insertion	1	1	1				
Abnormal labour	2			2	2		1
Abortion	62	25	62				
Abortion complete	4	2	4				
Abortion complicated	1		1				
Abortion early	19	13	19			1	2
Abortion incomplete	8	4	8				
Abortion late	10	7	10				

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abortion missed	117	40	117				
Abortion of ectopic pregnancy	3	2	3				
Abortion spontaneous	1846	551	1846			14	39
Abortion spontaneous complete	10	4	10				
Abortion spontaneous complicated	1		1				
Abortion spontaneous incomplete	2	1	2				
Abortion threatened	9	2	9			1	1
Afterbirth pain	1				1		
Amniorrhexis	9	3	6	2	3		
Amniorrhoea	9	1	6	1	3		
Amniotic cavity disorder	2		1		1		
Anaphylactoid syndrome of pregnancy	1		1				
Anembryonic gestation	26	8	22	2	4		
Arrested labour	3	1	2		1		
Biochemical pregnancy	3	1	1	1	2		
Birth trauma						1	1
Breech delivery	1		1				
Breech presentation						5	5
Cephalhaematoma	2	1	2				
Cephalo-pelvic disproportion	3		1	2	2		
Cervical dilatation	1				1		
Cervical incompetence	6	3	6				
Cervix dystocia	1		1				
Complication of delivery	2		2			1	1
Complication of pregnancy	11	2	5	3	6		
Decidual cast	10	3	6	3	4		
Delayed delivery	1	1	1				

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Eclampsia	2		2				1
Ectopic pregnancy	69	29	69			2	2
Face presentation	1		1				
False labour	1			1	1	1	1
First trimester pregnancy	1			1	1		
Foetal cardiac disorder	10	4	10				
Foetal damage	1		1				
Foetal death	155	46	155			3	5
Foetal disorder	5	1	5				
Foetal distress syndrome	11	7	11			2	3
Foetal growth abnormality	10	3	10				
Foetal growth restriction	124	43	124			6	6
Foetal hypokinesia	69	16	69			3	8
Foetal macrosomia	3	1	2	1	1		
Foetal malnutrition	1	1	1				
Foetal malpresentation	1				1		
Foetal-maternal haemorrhage	3	3	3				
Foetal vascular malperfusion	11	5	11				
Gestational diabetes	18	7	18			1	2
Gestational hypertension	10		6	3	4	2	2
Gestational trophoblastic detachment	3		3				
Haemorrhage foetal	1	1	1				
Haemorrhage in pregnancy	78	31	78			1	2
HELLP syndrome	15	6	15				1
High risk pregnancy	5	1	3	1	2		
Hydrops foetalis	8	1	8				
Hyperemesis gravidarum	7	3	7				1

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypothermia neonatal	1		1				
Imminent abortion	3	1	3				
Increased foetal movements	1			1	1		
Induced labour	7		1	4	6		
Intrapartum haemorrhage	3		3				1
Jaundice neonatal	17	4	8	5	9	1	2
Labour complication	5		1	1	4		
Labour pain	157	85	88	67	69		
Large for dates baby						2	2
Live birth	5		2	1	3		
Low birth weight baby	8	3	7	1	1		
Maternal condition affecting foetus	3	1	2	1	1		
Meconium in amniotic fluid	4	2	4				
Meconium stain	2	1	2				
Molar abortion	1	1	1				
Morning sickness	64	3	26	7	38		
Neonatal disorder	7			6	7		
Normal newborn	4			1	4		
Obstructed labour	1	1	1				
Oligohydramnios	14	3	14			2	2
Pelvic girdle pain	13	1	5	4	8		
Perinatal brain damage	1	1	1				
Peripartum cardiomyopathy	2	1	2				
Peripartum haemorrhage	3	2	3			1	1
Placental calcification	2	1	2				
Placental disorder	22	7	15	5	7		
Placental infarction	4		3	1	1		

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Placental insufficiency	11	9	11				
Placental necrosis	1	1	1				
Placenta praevia	3		3			1	1
Placenta praevia haemorrhage	5	1	5				
Polyhydramnios	5	2	5				
Poor weight gain neonatal	3			2	3		1
Post abortion haemorrhage	4	2	4				
Postpartum disorder	2				2		
Postpartum haemorrhage	26	3	13	3	13	2	2
Postpartum state	2				2		
Pre-eclampsia	34	13	27	4	7	4	8
Pregnancy	33	3	15	10	18		
Pregnancy after post coital contraception	4	1	4				
Pregnancy in habitual aborter	1				1		
Pregnancy of unknown location	1		1				
Pregnancy on contraceptive	8	4	8				
Pregnancy on oral contraceptive	14	6	14				
Pregnancy with contraceptive device	11	3	11				
Pregnancy with implant contraceptive	2		2				
Premature baby	184	59	142	24	42	9	12
Premature delivery	45	14	34	4	11		2
Premature labour	63	11	45	10	18	4	4
Premature rupture of membranes	36	13	31	4	5	1	3
Premature separation of placenta	27	10	27			2	3
Preterm premature rupture of membranes	27	5	22	4	5	1	2
Prolonged labour	3		1		2	3	3
Prolonged pregnancy	1				1	2	5

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pseudomenstruation neonatal	1			1	1		
Retained placenta or membranes	7	2	4		3	1	1
Retained products of conception	1	1	1				
Retroplacental haematoma	12	3	12			1	1
Risk of future pregnancy miscarriage	2	1	1		1		
Ruptured ectopic pregnancy	3	2	3				
Second trimester pregnancy						1	1
Shoulder dystocia	1		1				
Small for dates baby	10	4	7		3	1	1
Small size placenta	3	2	3				
Somatic symptom disorder of pregnancy	7		3	3	4		
Stillbirth	57	21	57				2
Subchorionic haematoma	5	1	5				
Subchorionic haemorrhage	2		2			1	1
Term birth	1			1	1		
Third stage postpartum haemorrhage	1	1	1				
Third trimester pregnancy	1				1		
Threatened labour	14	4	13		1		
Traumatic delivery	1	1	1				
Tubal rupture	1		1				
Twin pregnancy	4	1	1	1	3		
Umbilical cord abnormality	7		5	1	2		
Umbilical cord around neck	1		1				
Umbilical cord short	1	1	1				
Umbilical cord thrombosis	4	1	4				
Unintended pregnancy	23	2	7	10	16		
Unwanted pregnancy	8		2	3	6		

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Uterine atony	1		1				
Uterine contractions abnormal	43	6	17	11	26		
Uterine contractions during pregnancy	74	11	37	9	37		
Uterine hypertonus	32	2	9	5	23		
Uterine hypotonus	4	1	2	2	2		
Uterine irritability	1		1				
Vanishing twin syndrome							1
Vasa praevia						1	3
Weight decrease neonatal	3	1	2	1	1		
Total:	4056	1232	3596	241	460	85	149

System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Device breakage	8	2	6		2		
Device connection issue	25			2	25		
Device defective	1		1				
Device delivery system issue	1				1		
Device dislocation	5	2	5				
Device expulsion	12		2	3	10		
Device failure	4		1	3	3		
Device infusion issue	1		1				
Device issue	12			3	12		
Device leakage	2				2		
Device loosening	2		2				
Device malfunction	7		1	2	6		

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System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Device occlusion	3	2	2		1		1
Device pacing issue	1		1				
Device physical property issue	5		1	3	4		
Device power source issue							1
Device stimulation issue	1				1		
Device temperature issue	1				1		
Drug delivery system malfunction	1				1		
Electromagnetic interference	9		3	1	6		
Embedded device	2		1		1		
Lead dislodgement	1		1				
Liquid product physical issue	114			35	114		
Needle issue	128		4	11	124		1
Oversensing	51	7	22	9	29		
Patient-device incompatibility	3		1		2		
Physical product label issue	3			2	3		
Product adhesion issue	1			1	1		
Product after taste	21		3	4	18		
Product availability issue							1
Product closure issue	3			1	3		
Product colour issue	63			3	63		
Product complaint	78		4	15	74		
Product container issue	23			17	23		
Product container seal issue	7			6	7		
Product contamination	14			7	14		
Product contamination chemical	2		1		1		
Product contamination microbial	1		1				
Product contamination physical	78	1	2	20	76		

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System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Product counterfeit	1				1		
Product delivery mechanism issue	1			1	1		
Product deposit	7				7		
Product design issue	1	1	1				
Product expiration date issue	19			13	19		
Product formulation issue	5		1	2	4		
Product impurity	4				4		
Product label issue	27			18	27		
Product leakage	157			4	157		
Product lot number issue	15			5	15		
Product odour abnormal	8		2		6		
Product origin unknown	1		1				
Product outer packaging issue	1			1	1		
Product packaging issue	4			2	4		
Product packaging quantity issue	41			8	41		
Product physical consistency issue	1				1		
Product physical issue	25			12	25		
Product quality issue	174	5	6	47	168	1	1
Product reconstitution quality issue	10				10		
Product supply issue	31			2	31		
Product taste abnormal	18	1	2	4	16		
Product temperature excursion issue	14474	5	8	4627	14466	1	1
Suspected counterfeit product	42	1	1	10	41		
Suspected product contamination	3		1	1	2		
Suspected product quality issue	8	1	1		7		
Suspected product tampering	2			1	2		
Syringe issue	108			13	108		

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System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thrombosis in device	20	5	20				
Undersensing	8	1	4		4		
Total:	15910	34	114	4919	15796	2	6

System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aberrant motor behaviour	3	1	2		1		
Abnormal behaviour	204	16	86	31	118		1
Abnormal dreams	564	22	137	77	427	1	1
Abnormal sleep-related event	11	2	3	2	8		
Abulia	19	2	7	3	12		
Acrophobia	2			1	2		
Acute psychosis	17	4	17				
Acute stress disorder	5856	25	61	2710	5795		
Adjustment disorder	12	2	4	6	8		
Adjustment disorder with depressed mood	36	8	17	9	19		
Adjustment disorder with mixed anxiety and depressed mooc	1		1				
Aerophobia	1	1	1				
Affective ambivalence	1				1		
Affective disorder	105	11	23	34	82	1	1
Affect lability	169	5	31	56	138		
Aggression	240	19	81	76	159		1
Agitated depression	8		5		3		
Agitation	984	60	349	176	635		4
Agoraphobia	6		4	1	2		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Alcoholic hangover	2		1		1		
Alcoholic psychosis	1		1				
Alcoholism	13	2	13				
Alcohol problem	2		1		1		
Alcohol use disorder	1				1		
Alcohol withdrawal syndrome	1		1				
Alexithymia	1				1		
Alice in wonderland syndrome	3			3	3		
Anger	219	24	73	34	146	1	1
Anhedonia	27	2	9	9	18		
Anorexia nervosa	2			1	2		
Anorgasmia	9		7		2		
Anticipatory anxiety	5	1	1	1	4	1	1
Antisocial behaviour	2			1	2		
Antisocial personality disorder	1		1				
Anxiety	7049	763	2446	1380	4603	16	30
Anxiety disorder	139	14	39	54	100		
Anxiety disorder due to a general medical condition	2			1	2		
Apathy	913	52	192	423	721	1	2
Attention deficit hyperactivity disorder	36	1	12	8	24		
Attention-seeking behaviour	1		1				
Autism spectrum disorder	17	6	17				
Automatism	3		2	1	1		
Automatism epileptic	1		1				
Autoscopy	49	2	21	7	28		
Aversion	13	2	4		9		
Behaviour disorder	83	7	39	21	44		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Behaviour disorder due to a general medical condition	1		1				
Belligerence	2		1		1		
Binge drinking	1				1		
Binge eating	12		1	3	11		
Bipolar disorder	27	8	27				
Bipolar I disorder	11	2	11				
Bipolar II disorder	1		1				
Blunted affect	1				1		
Body dysmorphic disorder	3		2		1		
Borderline personality disorder	5		1	2	4		
Boredom	6		1	2	5		
Bradyphrenia	312	23	105	67	207		2
Breath holding	7	1	5	1	2		
Breathing-related sleep disorder	4		1	2	3		
Brief psychotic disorder with marked stressors	2	1	2				
Brief psychotic disorder without marked stressors	1		1				
Brief psychotic disorder, with postpartum onset	1	1	1				
Bruxism	68	6	25	8	43		
Bulimia nervosa	1		1				
Burnout syndrome	37	7	18	13	19		
Cardiovascular somatic symptom disorder	4	1	1	2	3		
Catastrophic reaction	2	1	2				
Catatonia	14	1	6	2	8		
Change in sustained attention	2				2		
Chronic idiopathic pain syndrome	5	1	1	1	4		
Clang associations	1				1		
Claustrophobia	20	3	6	6	14		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Clinomania	2			1	2		
Communication disorder	100	15	51	13	49		
Completed suicide	29	8	29				
Complex tic	1	1	1				
Compulsions	3	1	2		1		
Compulsive handwashing	1				1		
Compulsive hoarding	1				1		
Compulsive lip biting	1			1	1		
Confabulation	1		1				
Confusional arousal	2		1	1	1		
Confusional state	5539	510	2422	1064	3117	4	23
Constricted affect	7	3	5		2		
Conversion disorder	137	38	91	28	46		
Coprolalia	2	1	1		1		
Cyclothymic disorder	3		2		1		
Daydreaming	92	3	23	26	69		
Decreased eye contact	6	2	3		3		
Decreased interest	53	9	21	9	32		
Deja vu	9	2	5	2	4		
Delirium	613	116	613			2	2
Delirium febrile	24	10	24				
Delusion	123	15	58	22	65		
Delusional disorder, persecutory type	2		1		1		
Delusional disorder, unspecified type	4		2	1	2		
Delusional perception	18	2	12	2	6		
Delusion of grandeur	1		1				
Delusion of parasitosis	1	1	1				

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dependence	2	1	2				
Dependent personality disorder	1		1				
Depersonalisation/derealisation disorder	100	34	61	13	39		
Depressed mood	2037	125	558	550	1479		2
Depression	2054	270	809	511	1245	6	14
Depression suicidal	34	7	34			1	1
Depressive delusion	1		1				
Depressive symptom	51	7	20	16	31	1	1
Derailment	6	1	3	1	3		
Derealisation	121	13	44	34	77		
Dermatillomania	2			2	2		
Discouragement	35		1	9	34		
Disinhibition	9		4		5		
Disorganised speech	60	6	30	12	30		
Disorientation	1895	155	807	358	1088	1	8
Dissociation	153	14	56	24	97		1
Dissociative amnesia	10	2	5	2	5		
Dissociative disorder	33	3	16	4	17	1	1
Dissociative identity disorder	1				1		
Distractibility	45	5	18	10	27		
Disturbance in sexual arousal	17	1	7	6	10		
Disturbance in social behaviour	9			2	9		
Drug abuse	2	1	2				
Drug dependence	4	2	4				
Dysphemia	153	26	80	21	73		
Dysphonia psychogenic	1	1	1				
Dysphoria	502	10	201	51	301		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dyssomnia	5		1		4		
Eating disorder	595	37	188	97	407		2
Echolalia	1				1		
Echopraxia	1				1		
Emetophobia	1		1				
Emotional disorder	369	32	128	55	241	2	2
Emotional disorder of childhood	1		1				
Emotional distress	382	61	171	83	211		1
Emotional poverty	14	2	5	4	9		
Encopresis	2	1	2				
Enuresis	79	5	32	20	47	1	1
Epileptic psychosis	1	1	1				
Euphoric mood	230	8	50	29	180		
Excessive masturbation	1				1		
Excessive sexual fantasies	1			1	1		
Executive dysfunction	7	1	4	2	3		
Exhibitionism	1				1		
Exploding head syndrome	10		4	3	6		1
Factitious disorder	6		4		2		
Fear	492	48	148	93	344		
Fear of closed spaces	1		1				
Fear of death	148	28	56	42	92		
Fear of disease	18		4	8	14		
Fear of eating	4		2	1	2		
Fear of falling	23	1	6	6	17		
Fear of injection	64	1	5	10	59		
Fear of pregnancy	3			1	3		

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Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Fear-related avoidance of activities	5		2	2	3		
Feeling guilty	6	1	4	1	2		
Feeling of despair	171	7	33	69	138		1
Feelings of worthlessness	7	2	3	2	4		
Female orgasmic disorder	7	1	2	1	5		
Flashback	6		3		3		
Flat affect	44	6	16	7	28		
Flight of ideas	3		2	1	1		
Frustration tolerance decreased	119	9	22	27	97		1
Gastrointestinal somatic symptom disorder	2		1		1		
Gender dysphoria	1		1				
Generalised anxiety disorder	33	8	16	6	17		
Genito-pelvic pain/penetration disorder	4			3	4		
Grandiosity	1				1		
Grief reaction	8	1	2	3	6		
Habit cough	22	1	12	1	10		
Hallucination	931	241	931			1	5
Hallucination, auditory	112	30	112				2
Hallucination, gustatory	2	1	2				
Hallucination, olfactory	58	15	57	1	1		
Hallucinations, mixed	33	11	33			1	1
Hallucination, tactile	6		6				
Hallucination, visual	212	41	212			1	1
Head banging	50	6	39	2	11		
Helplessness	28		5	13	23		
Histrionic personality disorder	1			1	1		
Homicidal ideation	2				2		

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Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hostility	5	1	4		1		
Hydrophobia	2	1	1		1		
Hyperarousal	2				2		
Hypersexuality	3		1		2		
Hypersomnia-bulimia syndrome	3		2	1	1		
Hypervigilance	32		10	7	22	1	2
Hypnagogic hallucination	10	2	10				
Hypnopompic hallucination	3		3				
Hypomania	9	1	3	1	6		
Hyposomnia	8	2	4	1	4		
Illness anxiety disorder	9		1	3	8		
Illogical thinking	3	1	2	1	1		
Illusion	157	13	38	47	119		
Immunisation stress-related response	41	4	13	10	28		
Impaired reasoning	14		3	5	11		
Impatience	20	1	2	5	18		
Imperception	9	2	5	1	4		
Impulse-control disorder	7		2	2	5		
Impulsive behaviour	5	1	1	1	4		
Inappropriate affect	50	1	21	6	29		1
Indifference	21	5	11	3	10		
Inferiority complex	1				1		
Initial insomnia	569	29	86	155	483		2
Insomnia	16673	1192	4077	3639	12596	11	21
Intentional self-injury	25	9	25				
Intermittent explosive disorder	1				1		
Intrusive thoughts	17	2	10	2	7		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Irritability	2127	74	349	345	1778	1	2
Kinesiophobia	1	1	1				
Lack of spontaneous speech	41	4	27	1	14		
Laziness	57		7	7	50		
Learning disability	7		1	1	6		
Learning disorder	4	2	3		1		
Libido decreased	145	14	34	47	111		
Libido disorder	16	3	5	3	11		
Libido increased	41		3	12	38		
Limited symptom panic attack	1			1	1		
Listless	569	29	93	214	476		
Logorrhoea	18	2	9	2	9		1
Loss of dreaming	1			1	1		
Loss of libido	117	8	23	43	94		
Major depression	55	18	55				
Male orgasmic disorder	1			1	1		
Mania	55	1	24	6	31		
Manic symptom	2			2	2		
Mental disorder	471	51	163	129	308	1	4
Mental disorder due to a general medical condition	2		2				
Mental fatigue	544	81	302	87	242	2	5
Mental status changes	62	7	22	13	40		
Merycism	3			1	3		
Middle insomnia	745	60	202	202	543	4	5
Mixed anxiety and depressive disorder	31	6	15	8	16		
Mood altered	503	29	115	182	388		1
Mood disorder due to a general medical condition	3	1	3				

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mood swings	735	44	164	270	571		1
Morbid thoughts	9		3		6		1
Morose	11	2	3	4	8		
Mutism	85	13	50	7	35		
Mysophobia	1			1	1		
Nail picking	1			1	1		
Near death experience	207	49	207				
Negative thoughts	31	2	10	7	21		
Negativism	2			1	2		
Neglect of personal appearance	2		1		1		
Neologism	3			1	3		
Nervousness	1368	70	359	217	1009	2	5
Neuroleptic-induced deficit syndrome	1	1	1				
Neurologic somatic symptom disorder	2	1	1	1	1		
Neuropsychiatric symptoms	1		1				
Neuropsychiatric syndrome	1				1		
Neurosis	12	2	6	1	6		
Nicotine dependence	3		1		2		
Nightmare	793	43	210	159	583	2	3
Nocturnal fear	2			1	2		
Nosophobia	3		2	1	1		
Obsessive-compulsive disorder	18	1	8	4	10		
Obsessive-compulsive personality disorder	2		1		1		
Obsessive-compulsive symptom	2		1		1		
Obsessive rumination	1		1				
Obsessive thoughts	9	1	5	2	4		
Oppositional defiant disorder	1		1				

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Organic brain syndrome	12	3	10		2		
Orgasm abnormal	4		1		3		
Orgasmic sensation decreased	3		1	1	2		
Osmophobia	2	1	2				
Panic attack	1627	198	584	440	1043	4	9
Panic disorder	134	13	44	45	90		
Panic reaction	329	32	113	59	216		
Paralogism	1				1		
Paramnesia	7		5		2		
Paranoia	94	11	47	10	47		
Paranoid personality disorder	1				1		
Parasomnia	7		2	3	5		
Paroxysmal perceptual alteration	1				1		
Pathological doubt	1			1	1		
Performance fear	1		1				
Perinatal depression	5		4	1	1		
Persecutory delusion	9	3	6		3		
Perseveration	3	1	1		2		
Persistent depressive disorder	15	1	7	1	8		
Personality change	88	17	53	13	35		
Personality change due to a general medical condition	1			1	1		
Personality disorder	26	2	12	5	14		
Phantom vibration syndrome	1				1		
Phobia	23		2	12	21		
Phobia of driving							1
Phonophobia	83	10	32	21	51		1
Pica	2	1	1		1		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Poor quality sleep	1314	107	386	259	928	1	8
Poriomania	1				1		
Postpartum stress disorder	1	1	1				
Post stroke depression	1		1				
Post-traumatic amnestic disorder	3		2		1		
Post-traumatic stress disorder	50	9	29	10	21		
Posturing	2		1		1		
Poverty of speech	2	1	1		1		
Poverty of thought content	1				1		
Premature ejaculation	4		1	1	3		
Pressure of speech	4		2		2		
Procrastination	1			1	1		
Pseudodementia	2		2				
Pseudohallucination	3		1	1	2		
Psychiatric decompensation	13	4	7	1	6		
Psychiatric symptom	67	9	25	15	42	2	2
Psychogenic movement disorder	2		1		1		
Psychogenic pseudosyncope	3		2		1		
Psychogenic tremor	1				1		
Psychogenic visual disorder	1		1				
Psychological factor affecting medical condition	4		2	1	2		
Psychological trauma	19	1	5	7	14		
Psychomotor retardation	26	4	11	6	15		
Psychotic behaviour	5		4		1		
Psychotic disorder	147	30	99	20	48		
Psychotic disorder due to a general medical condition	3		3				
Psychotic symptom	10	3	10				

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Purging	1		1				
Rapid eye movement sleep behaviour disorder	2		1		1		
Reading disorder	71	5	17	22	54		
Restlessness	2249	130	537	695	1712	2	4
Schizoaffective disorder	2		2				
Schizoid personality disorder	1		1				
Schizophrenia	23	8	23				
School refusal	1			1	1		
Secondary tic	1			1	1		
Selective eating disorder	6	4	5		1		
Self-consciousness	5	1	2	1	3		
Self-destructive behaviour	1	1	1				
Self esteem decreased	24		5	10	19		1
Self-induced vomiting	1				1		
Self-injurious ideation	19	1	10	3	9		
Sense of a foreshortened future	6	1	4		2		
Sexual inhibition	2		1		1		
Sitophobia	1				1		
Sleep attacks	29	1	6	12	23		
Sleep disorder	4791	464	1217	1612	3574	6	10
Sleep disorder due to a general medical condition	80	12	29	11	51		
Sleep disorder due to general medical condition, hypersomni	2			1	2		
Sleep disorder due to general medical condition, insomnia ty	119	12	56	9	63		
Sleep inertia	4	1	3		1		
Sleep-related eating disorder	1				1		
Sleep talking	18		4	1	14		
Sleep terror	55	4	23	9	32	2	2

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Social anxiety disorder	10		3	5	7		
Social avoidant behaviour	22	2	9	7	13		
Social fear	3		2	1	1		
Social (pragmatic) communication disorder	2		1		1		
Soliloquy	14		4	1	10		
Somatic hallucination	1		1				
Somatic symptom disorder	127	11	45	29	82		
Somnambulism	46	5	10	12	36		
Somniphobia	2				2		
Sopor	54	8	41	1	13	1	4
Speech sound disorder	13		6	2	7		
Staring	43	6	29	4	14		
Stereotypy	5	1	4		1		
Stockholm syndrome	1				1		
Stress	975	112	324	219	651	6	13
Substance abuse	2	1	2				
Substance dependence	1		1				
Substance-induced psychotic disorder	3	1	3				
Suicidal behaviour	12	2	12				
Suicidal ideation	379	104	379			1	2
Suicide attempt	57	18	57				
Suicide threat	6	3	6				
Suspected suicide	1		1				
Suspiciousness	3		1		2		
Tachyphrenia	37	4	12	3	25		
Taciturnity	1			1	1		
Tearfulness	125	19	68	13	57		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tension	421	29	104	87	317		1
Terminal insomnia	68	3	18	11	50		
Thanatophobia	3		1		2		
Thermophobia	4		1	1	3		
Thinking abnormal	361	28	99	59	262		
Thought blocking	9	2	4	2	5		
Tic	161	29	71	45	90		
Time perception altered	15	1	5	3	10		
Trance	7		1	1	6		
Transvestism	1				1		
Trichotillomania	3				3		
Verbigeration	1				1		
Violence-related symptom	3		1		2		
Vomiting psychogenic	1		1				
Waxy flexibility	1		1				
Total:	77148	6521	24027	18332	53121	92	227

System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute kidney injury	835	242	835			1	3
Albuminuria	15	4	10	3	5		
Anti-glomerular basement membrane disease	6	4	6				
Anuria	98	27	98				1
Atonic urinary bladder	1		1				
Autoimmune nephritis	1		1				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Automatic bladder	1	1	1				
Azotaemia	25	7	25				
Bence Jones proteinuria	1		1				
Bilirubinuria	5		4	1	1		
Bladder cyst	1	1	1				
Bladder dilatation	16	3	10	2	6		
Bladder discomfort	70	6	13	22	57		
Bladder disorder	107	16	54	15	53		1
Bladder diverticulum	1				1		
Bladder dysfunction	28	4	18	6	10		
Bladder fibrosis	1		1				
Bladder hypertrophy	5	2	3		2		
Bladder irritation	47	7	18	16	29		
Bladder mass	1	1	1				
Bladder necrosis	1		1				
Bladder obstruction	5		5				
Bladder pain	164	13	52	50	112		1
Bladder prolapse	3	1	2		1		
Bladder spasm	23	2	8	2	15		
Bladder sphincter atony	16	1	11	5	5		
Bladder tamponade	2	1	2				
Bladder ulcer	1		1				
Bullous oedema of the bladder	1				1		
C3 glomerulopathy	3	3	3				
Calculus bladder	10	1	4	4	6		1
Calculus urinary	18	3	5	2	13	1	1
Choluria	20		9	1	11		

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chromaturia	501	47	152	103	349		1
Chronic kidney disease	140	39	140				
Costovertebral angle tenderness	10	1	2	1	8		
Crush syndrome	2	1	2				
Crystalluria	1		1				
Cystitis glandularis	2		2				
Cystitis haemorrhagic	39	11	39				1
Cystitis interstitial	27	4	15	7	12	1	1
Cystitis-like symptom	12		1	3	11		
Cystitis noninfective	309	15	30	197	279	4	5
Diabetic nephropathy	11	7	8	2	3	1	1
Dysuria	821	66	278	174	543	1	6
End stage renal disease	18	12	18				
Focal segmental glomerulosclerosis	21	10	19		2		
Foetal renal impairment	1	1	1				
Follicular cystitis	1	1	1				
Genitourinary symptom	6		6				
Glomerulonephritis	83	46	83				
Glomerulonephritis acute	12	4	12				
Glomerulonephritis chronic	7	3	7				
Glomerulonephritis membranoproliferative	7	5	7				
Glomerulonephritis membranous	22	12	22				
Glomerulonephritis minimal lesion	59	25	59				1
Glomerulonephritis proliferative	2	1	2				
Glomerulonephritis rapidly progressive	32	10	32				
Glomerulonephropathy	2		2				
Glomerulosclerosis	2		2				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glycosuria	6	1	3	3	3		
Goodpasture's syndrome	7	4	7				
Haematinuria	1				1		
Haematuria	894	111	392	195	502		3
Haemoglobinuria	8	4	8				
Haemorrhage urinary tract	93	19	93			1	1
Henoch-Schonlein purpura nephritis	4	3	4				
Hydronephrosis	23	7	23			1	2
Hypertensive nephropathy	2		2				
Hypertonic bladder	35	5	7	12	28		
Hypotonic urinary bladder	2		2				
IgA nephropathy	89	48	89			1	1
Immune-mediated cystitis	1		1				
Incontinence	271	32	131	48	140	1	1
Ketonuria	4		3		1		
Kidney congestion	6	1	4	2	2		
Kidney enlargement	12	3	7	1	5		
Kidney fibrosis	3	2	3				
Kidney hypermobility	1				1		
Kidney small	2		1		1		
Leukocyturia	40	9	24	2	16		
Loss of bladder sensation	11	2	9	1	2		
Lower urinary tract symptoms	11		4	3	7		
Lupus nephritis	13	4	13				
Mesangioproliferative glomerulonephritis	3	1	3				
Microalbuminuria	6		2	3	4		
Micturition disorder	82	14	24	17	58		1

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Renal and urinary disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Micturition frequency decreased	8	2	2	2	6		
Micturition urgency	387	38	121	126	266		
Mixed incontinence	3			1	3		
Myeloma cast nephropathy	1		1				
Myoglobinuria	5	2	5				
Nephrectasia	1	1	1				
Nephritic syndrome	13	9	13				
Nephritis	108	46	108			2	2
Nephritis allergic	1		1				
Nephroangiosclerosis	1	1	1				
Nephrocalcinosis	2	1	2				
Nephrogenic diabetes insipidus	1		1				
Nephrolithiasis	222	97	221		1	10	17
Nephropathy	44	9	28	9	16		
Nephropathy toxic	2			1	2		
Nephrosclerosis	7		7				
Nephrotic syndrome	290	98	290			1	3
Neurogenic bladder	20	4	20				1
Nocturia	77	8	20	19	57		1
Oedematous kidney	2	2	2				1
Oliguria	84	13	41	14	43	1	2
Page kidney	1			1	1		
Paroxysmal nocturnal haemoglobinuria	9	4	9				
Pelvi-ureteric obstruction	1	1	1				
Perinephric collection	1			1	1		1
Perinephric oedema	1		1				
Pollakiuria	949	67	256	199	693	3	5

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Polyuria	234	6	59	51	175	1	1
Postrenal failure	1		1				
Post streptococcal glomerulonephritis	1	1	1				
Prerenal failure	17	3	17				
Proteinuria	255	39	125	70	130	1	3
Pulmonary renal syndrome	2		2				
Pyelocaliectasis	4	2	4				1
Renal aneurysm	3		1	1	2		
Renal arteriosclerosis	1	1	1				
Renal artery dissection	1		1				
Renal artery occlusion	1	1	1				
Renal artery stenosis	6	3	6				
Renal artery thrombosis	16	4	16				
Renal atrophy	9	3	9				
Renal colic	123	17	64	19	59	3	3
Renal cortical necrosis	2	1	2				
Renal cyst	74	7	28	9	46		
Renal cyst haemorrhage	2		2				
Renal disorder	289	41	142	63	147	4	8
Renal embolism	7	1	7				
Renal failure	672	195	672			5	5
Renal failure neonatal	1		1				
Renal haematoma	1		1				
Renal haemorrhage	19	9	19				
Renal hypertension	2	1	1	1	1		
Renal hypertrophy	4	1	2	1	2		
Renal impairment	400	113	400			1	5

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Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Renal infarct	70	23	70				1
Renal injury	20	6	19	1	1		
Renal ischaemia	11	3	11				
Renal-limited thrombotic microangiopathy	2		2				
Renal mass	6		3	3	3		
Renal necrosis	3		3				
Renal pain	1950	144	518	678	1432	1	2
Renal tubular atrophy	1	1	1				
Renal tubular disorder	3	2	3				
Renal tubular injury	3	2	3				
Renal tubular necrosis	19	7	19				
Renal vascular thrombosis	7	2	7				
Renal vasculitis	8	5	8				1
Renal vein embolism	1	1	1				
Renal vein occlusion	3	1	3				
Renal vein thrombosis	20	8	20				
Scleroderma renal crisis	2		2				
Semenuria	1				1		
Single functional kidney							1
Strangury	10	3	5	1	5	1	3
Stress urinary incontinence	19	2	3	5	16		
Subacute kidney injury	1	1	1				
Tubulointerstitial nephritis	85	44	85				
Tubulointerstitial nephritis and uveitis syndrome	2		2				
Ureteral disorder	1		1			1	1
Ureteral wall thickening	1	1	1				
Ureteric dilatation	4	1	3	1	1		1

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Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ureteric obstruction	3	1	3				
Ureteric stenosis	3		3				
Ureterolithiasis	7	1	5	1	2		1
Urethral caruncle	1		1				
Urethral disorder	7	1	3	1	4		
Urethral fistula	1		1				
Urethral haemorrhage	7	2	7				1
Urethral intrinsic sphincter deficiency	2	1	2				
Urethral obstruction	1	1	1				
Urethral pain	21	2	8	5	13		
Urethral polyp	1				1		
Urethral spasm	2		1	1	1		
Urethral stenosis	3	2	3				
Urethral syndrome	2			1	2		
Urethritis noninfective	5		1	1	4	1	1
Urge incontinence	17	1	7	5	10		
Urinary bladder atrophy	1	1	1				
Urinary bladder haematoma	1		1				
Urinary bladder haemorrhage	31	8	31				
Urinary bladder polyp	1			1	1		
Urinary bladder rupture	2		2				
Urinary hesitation	26	6	11	5	15	1	2
Urinary incontinence	751	94	348	148	403		2
Urinary retention	348	85	347	1	1		1
Urinary straining	10		1	5	9		
Urinary tract discomfort	24	3	4	9	20		
Urinary tract disorder	49	1	8	21	41	1	1

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Urinary tract inflammation	46	4	18	12	28		
Urinary tract obstruction	12	7	12				
Urinary tract pain	27	1	9	8	18		
Urine abnormality	105	5	27	30	78		2
Urine flow decreased	30	5	15	4	15		1
Urine odour abnormal	136	9	28	32	108		
Urinoma	2		2				
Urogenital disorder	3			1	3		
Urogenital fistula	1		1				
Urogenital haemorrhage	3		3				
Urothelium erosion	1	1	1				
Vesicoureteric reflux	1	1	1				
Total:	13647	2293	7454	2472	6193	51	114

System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal uterine bleeding	114	15	29	39	85		
Abnormal withdrawal bleeding	273	4	6	71	267		
Acquired hydrocele	1		1				
Acquired phimosis	3		1	1	2		
Adenomyosis	62	18	26	20	36		
Adnexal torsion	8	4	8				
Adnexa uteri cyst	1			1	1		
Adnexa uteri mass	2	1	2				
Adnexa uteri pain	660	52	155	223	505	1	1

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Amenorrhoea	12404	454	1143	5381	11261	2	2
Anisomastia	7		1	2	6		
Asherman's syndrome	1				1		
Aspermia	2				2		
Asthenospermia	2			2	2		
Atrophic vulvovaginitis	6	1	2	3	4		
Azoospermia	3	1	2	1	1		
Balanoposthitis	25	2	6	8	19		
Bartholin's cyst	11	5	6	2	5		
Benign prostatic hyperplasia	32	7	17	4	15	1	1
Bleeding anovulatory	3		1		2		
Breast atrophy	11	1	1	2	10		
Breast calcifications	3		1		2	1	1
Breast cyst	134	9	39	49	95		
Breast discharge	79	5	12	34	67		
Breast discolouration	8	1	3	2	5		
Breast discomfort	496	23	73	161	423		
Breast disorder	74	6	20	26	54		
Breast disorder female	20		5	4	15		
Breast disorder male	1				1		
Breast dysplasia	2	1	1		1		
Breast engorgement	188	5	13	117	175		
Breast enlargement	566	18	69	222	497		
Breast fibrosis	2		1		1		
Breast haematoma	27	2	10	4	17		
Breast haemorrhage	11	2	11				
Breast hyperplasia	6	1	4		2		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Breast induration	43	1	4	21	39		
Breast inflammation	233	16	46	83	187	1	1
Breast mass	534	56	186	119	348	2	3
Breast milk discolouration	21	3	7	1	14		
Breast milk odour abnormal	6			3	6		
Breast necrosis	3	2	3				
Breast oedema	120	10	23	47	97		
Breast pain	5296	323	1193	1697	4103	7	16
Breast swelling	1478	90	294	414	1184		
Breast tenderness	897	40	131	304	766		1
Breast ulceration	3	2	2	1	1		
Cervical cyst	2			1	2		
Cervical discharge	6		2	1	4		
Cervical dysplasia	12	5	7	4	5		
Cervical friability	2			2	2		
Cervical polyp	6	1	4	1	2		
Cervix disorder	9		3	3	6		
Cervix enlargement	1		1				
Cervix erythema	1		1				
Cervix haematoma uterine	1		1				
Cervix haemorrhage uterine	12	2	12				
Cervix inflammation	3		1		2		
Cervix oedema	3			1	3		
Clitoral engorgement	2		1		1		
Coital bleeding	55	6	13	20	42		
Cystocele	2			1	2		
Dysmenorrhoea	15319	920	3706	5536	11613	3	17

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dyspareunia	28	2	9	11	19		
Ectropion of cervix	8	1	2	2	6		
Ejaculation delayed	1	1	1				
Ejaculation disorder	20	3	7	5	13		
Ejaculation failure	20		6	7	14		
Endometrial atrophy	5	1	3	2	2		
Endometrial disorder	21	7	13	5	8		
Endometrial dysplasia	1	1	1				
Endometrial hyperplasia	18	4	8	9	10		
Endometrial hypertrophy	1				1		
Endometrial hypoplasia	3		1	1	2		
Endometrial thickening	44	9	17	11	27		
Endometriosis	371	78	195	84	176		1
Epididymal cyst	4	1	4				
Epididymal disorder	1				1		
Epididymal enlargement	1		1				
Epididymal tenderness	4	2	3		1		
Erectile dysfunction	506	215	506			4	7
Erection increased	25		5	10	20		
Fallopian tube disorder	7		2	3	5		
Female genital tract fistula	2		2				
Female reproductive tract disorder	10	1	3	5	7		
Female sexual arousal disorder	1			1	1		
Female sexual dysfunction	5		3		2		
Fibrocystic breast disease	13	2	5	6	8		
Foreskin oedema	1	1	1				
Galactorrhoea	73	6	17	30	56		1

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Galactostasis	54	1	7	22	47		
Genital anaesthesia	3	2	2	1	1		
Genital blister	19	1	4	7	15		
Genital burning sensation	49	5	14	18	35		
Genital cyst	1	1	1				
Genital discharge	12			9	12		
Genital discolouration	2	1	1		1		
Genital discomfort	24	2	3	11	21		
Genital disorder	2			1	2		
Genital dysaesthesia	1	1	1				
Genital erosion	3	1	1	1	2		
Genital erythema	17		3	4	14		
Genital exfoliation	2			2	2		
Genital haemorrhage	130	37	130				
Genital hyperaesthesia	2		1		1		
Genital hypoaesthesia	10	4	6		4		
Genital lesion	12		1	3	11		
Genital macule	1	1	1				
Genital odour	2				2		
Genital pain	123	10	28	52	95		
Genital paraesthesia	16	2	4	5	12		
Genital rash	49	3	10	16	39	3	3
Genitals enlarged	2		1	1	1		
Genital swelling	35	6	14	6	21		
Genital tract inflammation	24	2	6	7	18		
Genital ulceration	48	9	22	8	26		
Gynaecomastia	70	3	11	29	59		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haematosalpinx	1		1				
Haematospermia	48	4	12	14	36		
Haemorrhagic breast cyst	2		2				
Haemorrhagic ovarian cyst	20	6	20				
Heavy menstrual bleeding	30500	1707	6364	11206	24136	4	16
Hydrometra	3		2		1		
Hydrosalpinx	5	2	5				
Hypomenorrhoea	2857	107	400	1017	2457		2
Inadequate lubrication	1				1		
Infertility	70	19	35	14	35		
Infertility female	29	7	15	11	14		
Infertility male	3	2	3				
Intermenstrual bleeding	13818	401	1355	5683	12463	3	5
Labia enlarged	6	1	2	2	4		
Lactation disorder	127	5	15	64	112		
Lactation puerperal increased	49		5	24	44		
Male sexual dysfunction	1			1	1		
Mammary duct ectasia	6		1	2	5		
Mastoptosis	2		2				
Menometrorrhagia	834	65	137	438	697		
Menopausal disorder	10	3	5	3	5		
Menopausal symptoms	259	18	50	92	209		
Menopause delayed	6	1	2	3	4		
Menstrual discomfort	1419	24	62	792	1357		
Menstrual disorder	24427	868	2360	11706	22067	3	9
Menstruation delayed	15101	600	2412	4554	12689	3	10
Menstruation irregular	16535	858	2813	6487	13722	2	12

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Metrorrhoea	3		2	1	1		
Nipple disorder	29	3	6	8	23	1	1
Nipple enlargement	2		1		1		
Nipple exudate bloody	10	1	2	3	8		
Nipple inflammation	20	4	5	6	15		
Nipple oedema	2				2		
Nipple pain	325	9	49	95	276	1	1
Nipple swelling	51		4	16	47		
Nocturnal emission	3			2	3		
Noninfective epididymitis	1			1	1		
Noninfective oophoritis	25	10	25				
Oedema genital	21	4	9	4	12		
Oligoasthenoteratozoospermia	1	1	1				
Oligomenorrhoea	3716	142	325	1821	3391		
Oligospermia	3	1	2	1	1		
Orchitis noninfective	20	4	6	5	14		
Organic erectile dysfunction	17		10		7		
Ovarian atrophy	1			1	1		
Ovarian cyst	272	51	103	91	169	1	1
Ovarian cyst ruptured	49	19	49				
Ovarian cyst torsion	1		1			1	1
Ovarian disorder	22	2	8	6	14		
Ovarian enlargement	15		4	4	11		
Ovarian failure	17	6	7	4	10		
Ovarian haematoma	1		1				
Ovarian haemorrhage	18	5	18				
Ovarian hyperfunction	1				1		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ovarian hyperstimulation syndrome	1	1	1				
Ovarian mass	4	2	4				
Ovarian necrosis	2	2	2				
Ovarian oedema	1			1	1		
Ovarian prolapse	2	1	2				
Ovarian rupture	1	1	1				
Ovarian vein thrombosis	16	5	16				
Ovulation disorder	110	14	28	41	82		
Ovulation pain	376	24	86	152	290		
Painful ejaculation	5	2	3		2		
Painful erection	7	2	3	3	4		
Pelvic adhesions	1				1		
Pelvic congestion	4	1	1		3		
Pelvic cyst	1			1	1		
Pelvic discomfort	35	5	12	7	23		
Pelvic floor muscle weakness	8	1	3	1	5		
Pelvic fluid collection	5	3	5				
Pelvic haematoma	2		1		1		
Pelvic haemorrhage	26	3	26				
Pelvic organ prolapse	3	1	1		2		
Pelvic pain	1170	89	296	432	874		3
Penile blister	7	2	3		4		
Penile burning sensation	3				3		
Penile curvature	1				1		
Penile discharge	5			3	5		
Penile discomfort	5	1	1	1	4		
Penile erosion	1		1				

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Penile erythema	10		1	3	9		
Penile exfoliation	4			1	4		
Penile haematoma	4		1	1	3		
Penile haemorrhage	12	1	12				
Penile oedema	15	2	8	4	7		
Penile pain	33	2	8	7	25		
Penile rash	8	1	1	2	7		
Penile size reduced	6			4	6		
Penile swelling	25	4	10	5	15		
Penile vascular disorder	3			1	3		
Penile vein thrombosis	12	5	12				
Penis disorder	34	1	8	12	26		
Perineal disorder	6	1	3	1	3		
Perineal erythema	1		1				
Perineal pain	15	1	6	4	9		
Perineal rash	2		1		1		
Perineal ulceration	2	1	2				
Peyronie's disease	10	2	4	3	6		
Plasma cell mastitis	3		2		1		
Polycystic ovaries	85	14	46	15	39		
Polymenorrhagia	15		5	7	10		
Polymenorrhoea	10668	336	896	4513	9772	1	6
Poor milk ejection reflex	14			12	14		
Postmenopausal haemorrhage	2703	1135	2703			1	7
Premature follicular ripening	1				1		
Premature menopause	62	9	26	22	36		
Premature ovulation	27	1	3	10	24		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Premenstrual dysphoric disorder	47	6	25	10	22		
Premenstrual headache	46	1	7	19	39		
Premenstrual pain	632	35	140	218	492		
Premenstrual syndrome	1075	70	239	390	836		
Priapism	20	1	7	5	13		
Prostate tenderness	1			1	1		
Prostatic atrophy	1			1	1		
Prostatic calcification	1			1	1		
Prostatic cyst	2	1	1		1		
Prostatic disorder	15	3	4	4	11		
Prostatic haemorrhage	1	1	1				
Prostatic obstruction	1		1				
Prostatic pain	8	3	4	2	4		
Prostatism	1				1		
Prostatitis	106	17	52	27	54		
Prostatomegaly	19	2	6	2	13		
Pruritus genital	71	5	15	30	56		
Red breast syndrome	1				1		
Reproductive tract disorder	7	2	2	2	5		
Retracted nipple	3			2	3		
Retrograde menstruation	10	1	1	3	9		
Scrotal angiokeratoma	2				2		
Scrotal dermatitis	2				2		
Scrotal discomfort	4			1	4		
Scrotal disorder	3		1		2		
Scrotal erythema	11	2	5	1	6		
Scrotal exfoliation	4		2	1	2		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Scrotal haemorrhage	1				1		
Scrotal inflammation	3		1	1	2		
Scrotal irritation	1			1	1		
Scrotal oedema	10	2	6	1	4		
Scrotal pain	40	4	20	4	20		
Scrotal swelling	27	6	10	7	17		
Scrotal ulcer	2	2	2				
Scrotum erosion	1		1				
Semen discolouration	2		1	1	1		
Sexual dysfunction	38	4	15	14	23		
Shortened cervix	4		2	1	2		
Spermatic cord haemorrhage	1		1				
Spermatic cord obstruction	1			1	1		
Spermatocele	2		1		1		
Spontaneous ejaculation	2			1	2		
Spontaneous penile erection	15		1	3	14		
Superovulation	4	1	2	1	2		
Suppressed lactation	590	20	67	344	523		
Testicular appendage torsion	1			1	1		
Testicular atrophy	1	1	1				
Testicular cyst	3			1	3		
Testicular disorder	24	5	11	3	13		
Testicular haemorrhage	2	1	2				
Testicular hypertrophy	1				1		
Testicular infarction	3	1	3				
Testicular mass	1			1	1		
Testicular microlithiasis	1				1		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Testicular necrosis	1		1				
Testicular oedema	5		2	1	3		
Testicular pain	385	35	110	114	275		
Testicular retraction	2	1	2				
Testicular swelling	96	11	30	27	66		
Testicular torsion	9	4	9				
Testis discomfort	15		3	4	12	1	1
Thrombosis corpora cavernosa	1		1				
Uterine adhesions	1		1				
Uterine cervix hyperplasia	1	1	1				
Uterine cyst	13	2	4	7	9		
Uterine disorder	26	1	5	10	21		
Uterine enlargement	13	3	5	2	8		
Uterine haematoma	6	1	2	4	4		1
Uterine haemorrhage	248	82	248			2	2
Uterine inflammation	36	5	20	7	16		
Uterine ischaemia	1		1				
Uterine malposition	2			1	2		
Uterine mass	3		1	1	2		
Uterine pain	302	14	61	102	241		
Uterine polyp	42	9	24	10	18		
Uterine prolapse	4	1	3		1		
Uterine spasm	235	17	56	81	179		
Uterine tenderness	8	1	2	3	6		
Vaginal cyst	10		5	2	5		
Vaginal discharge	517	23	81	177	436	1	1
Vaginal disorder	12		2	3	10		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaginal erosion	2		1	1	1		
Vaginal fistula						1	1
Vaginal haematoma	2		1		1		
Vaginal haemorrhage	5034	324	1333	1431	3701	1	15
Vaginal lesion	7		2	1	5		
Vaginal mucosal blistering	4	1	4				
Vaginal odour	23	3	4	13	19		
Vaginal oedema	2	1	1	1	1		
Vaginal polyp	1		1				
Vaginal prolapse	1		1				
Vaginal ulceration	30	3	10	14	20		
Varicocele	14	5	10	2	4		
Varicose veins pelvic	3			1	3		
Varicose veins vaginal	3	1	2	1	1		
Varicose veins vulval	5			3	5		
Vulva cyst	2	1	1	1	1		
Vulval disorder	17	2	5	8	12		
Vulval eczema	3	2	3				
Vulval haematoma	1	1	1				
Vulval haemorrhage	34	9	34				
Vulval oedema	8		2		6		
Vulval ulceration	61	11	22	16	39		
Vulvar dysplasia	1		1				
Vulvar erosion	1				1		
Vulvovaginal burning sensation	68	8	21	14	47		
Vulvovaginal discomfort	70	5	16	21	54		
Vulvovaginal disorder	2			2	2		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vulvovaginal dryness	63	7	12	23	51	1	1
Vulvovaginal erythema	18	1	2	5	16		
Vulvovaginal exfoliation	1			1	1		
Vulvovaginal inflammation	22	5	7	5	15		
Vulvovaginal pain	215	25	61	67	154		
Vulvovaginal pruritus	78	7	20	21	58		
Vulvovaginal rash	8	2	4		4		
Vulvovaginal swelling	39	5	14	8	25		
Vulvovaginal ulceration	6	1	5	1	1		
Withdrawal bleed	43	2	9	12	34		
Total:	178353	10018	32320	67820	146033	53	151

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acquired diaphragmatic eventration	4		4				
Acute chest syndrome	4	1	4				
Acute lung injury	4	2	4				
Acute pulmonary oedema	147	39	147				1
Acute respiratory distress syndrome	258	84	258				
Acute respiratory failure	309	92	309			1	3
Adenoidal disorder	20			9	20		
Adenoidal hypertrophy	2		2				
Agonal respiration	10	1	10				
Allergic bronchitis	6		3		3		
Allergic cough	31	2	11	9	20		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Allergic pharyngitis	4		3		1		
Allergic respiratory disease	6	1	3	1	3		
Allergic respiratory symptom	21	1	8	2	13		
Allergic sinusitis	12	1	3		9		
Alveolar lung disease	5	2	5				
Alveolar proteinosis	1				1		
Alveolitis	18	8	18				
Anoxia	4	2	4				
Aphonia	877	56	274	169	603		2
Apnoea	170	42	170				
Apnoeic attack	8	2	8				
Asphyxia	160	25	160				
Aspiration	103	17	103			1	1
Aspirin-exacerbated respiratory disease	2	1	1		1		
Asthma	3395	416	1533	689	1862	3	11
Asthma-chronic obstructive pulmonary disease overlap synd	3	1	1	1	2		
Asthma exercise induced	23	2	7	7	16		
Asthma late onset	3		2		1		
Asthmatic crisis	237	70	237			3	12
Atelectasis	127	22	80	21	47		
Autoimmune lung disease	4	1	4				
Bendopnoea	1		1				
Bradypnoea	11	2	8	1	3		
Brief resolved unexplained event	1	1	1			1	1
Bronchial disorder	60	5	22	17	38	1	1
Bronchial dysplasia	1		1				
Bronchial haemorrhage	4	3	4				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bronchial hyperreactivity	51	5	20	8	31		
Bronchial irritation	15		1	7	14		
Bronchial obstruction	20	8	20				
Bronchial oedema	4	1	4				
Bronchial secretion retention	18	3	8	3	10		
Bronchial wall thickening	13		6	4	7		
Bronchiectasis	44	14	44			1	1
Bronchitis chronic	26	4	10	7	16		
Bronchopleural fistula	1		1				1
Bronchopneumopathy	24	3	15	5	9		
Bronchopulmonary disease	2				2		
Bronchopulmonary dysplasia						1	1
Bronchospasm	802	62	467	44	335	2	3
Bronchostenosis	23	7	23				
Catarrh	172	15	44	32	128	1	1
Cheyne-Stokes respiration	6		6				
Childhood asthma	2				2		
Choking	231	47	231			1	2
Choking sensation	284	36	133	45	151		1
Chronic hyperplastic eosinophilic sinusitis	1		1				
Chronic obstructive pulmonary disease	356	47	248	33	108		5
Chronic respiratory disease	7		1	1	6		
Chronic respiratory failure	15	4	15				
Combined pulmonary fibrosis and emphysema	1		1				
Cough	26605	1363	6304	6714	20301	41	96
Cough decreased	5			1	5		
Cough variant asthma	46	5	22	7	24		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cyanosis central	3		3				
Cyanosis neonatal							1
Cystic lung disease	4		1	1	3		
Dependence on respirator	13	7	13				
Diaphragmalgia	108	9	27	28	81		
Diaphragmatic abnormal relaxation	1			1	1		
Diaphragmatic disorder	22	2	7	5	15		
Diaphragmatic paralysis	10	6	10				
Diaphragmatic rupture	1		1				
Diaphragmatic spasm	17	2	7	3	10		
Diaphragm muscle weakness	3		2		1		
Diffuse alveolar damage	8		8				
Diffuse panbronchiolitis	1	1	1				
Dry lung syndrome	1		1				
Dry throat	856	23	186	153	670		3
Dysaesthesia pharynx	3				3		
Dysphonia	2802	131	853	458	1949	3	10
Dyspnoea	56775	6875	22303	14791	34472	66	192
Dyspnoea at rest	255	88	255			2	7
Dyspnoea exertional	2846	463	1255	795	1591	11	25
Dyspnoea paroxysmal nocturnal	24	6	13	2	11		
Ear, nose and throat disorder	3	1	2	1	1		
Egobronchophony	1				1		
Emphysema	111	12	50	25	61		
Eosinophilic bronchitis	2		2				
Eosinophilic pleural effusion	2	1	2				
Eosinophilic pneumonia	32	13	32				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Eosinophilic pneumonia acute	4	2	4				
Eosinophilic pneumonia chronic	3	3	3				
Epiglottic oedema	19	5	19				
Epistaxis	5371	284	1152	1356	4219	2	11
Gasping syndrome	2	1	2				
Glottal incompetence	1		1				
Granulomatous pneumonitis	1	1	1				
Grunting	41		19	2	22		
Haemoptysis	593	88	329	71	264	1	1
Haemothorax	11	4	11				
Hiccups	175	13	51	38	124		1
Hydrothorax	17	5	17				
Hyperactive pharyngeal reflex	6		2	3	4		
Hypercapnia	39	5	29	3	10		
Hyperoxia	3		1		2		
Hypersensitivity pneumonitis	23	7	23				
Hyperventilation	1130	85	515	150	615		3
Hypocapnia	11		7		4		
Hypopnoea	383	36	216	50	167		
Hypoventilation	95	59	95			4	5
Hypoxia	599	131	599			2	4
Idiopathic interstitial pneumonia	2	1	2				
Idiopathic pulmonary fibrosis	23	6	23				1
Immune-mediated lung disease	6	3	6				
Increased bronchial secretion	59	5	21	11	38		
Increased upper airway secretion	166	15	59	26	107		
Increased viscosity of bronchial secretion	19	2	9	2	10		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Increased viscosity of upper respiratory secretion	102	4	30	32	72		
Infantile apnoea	2		2			1	1
Interstitial lung disease	340	98	340			1	5
Intranasal hypoaesthesia	9		2	2	7		
Intranasal paraesthesia	20		2	3	18		
Irregular breathing	89	8	38	14	51		
Laryngeal atrophy	1		1				
Laryngeal discomfort	156	5	48	23	108		
Laryngeal disorder	17		11	1	6		
Laryngeal dyspnoea	9	1	9				
Laryngeal erythema	3		2		1		
Laryngeal haematoma	3	1	1	1	2		
Laryngeal haemorrhage	2	1	2				
Laryngeal inflammation	37	1	5	15	32		1
Laryngeal mass	2				2		
Laryngeal obstruction	21		21				
Laryngeal oedema	498	61	497		1	2	8
Laryngeal pain	79	3	20	10	59		
Laryngeal stenosis	16	3	16				
Laryngeal ulceration	1		1				
Laryngitis allergic	3		2		1		
Laryngospasm	143	16	91	16	52		2
Laryngotracheal oedema	1		1				
Larynx irritation	73		22	10	51		
Loeffler's syndrome	3		1	2	2		
Lower respiratory tract congestion	69	8	31	11	38	1	1
Lower respiratory tract inflammation	4	1	2	1	2		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lung consolidation	32	5	25	5	7		
Lung cyst	3		1		2		
Lung diffusion disorder	8	2	3	4	5		
Lung disorder	749	99	367	143	382	2	3
Lung hernia	1				1		
Lung hyperinflation	19	2	11	3	8		
Lung infiltration	129	29	96	9	33		
Lung opacity	102	20	71	9	31		
Lung perforation	1	1	1				
Meconium aspiration syndrome	2		2				1
Mediastinal cyst	1	1	1				
Mediastinal disorder	7	2	2		5		
Mediastinal effusion	1		1				
Mediastinal haematoma	1				1		
Mediastinal haemorrhage	3		3				
Mediastinal mass	5	1	4		1		
Middle lobe syndrome	2		1	1	1		
Mouth breathing	20	1	10	4	10		
Multifocal micronodular pneumocyte hyperplasia	1			1	1		
Nasal cavity mass	1			1	1		
Nasal congestion	4057	123	663	859	3394	6	13
Nasal crusting	23		1	9	22		
Nasal cyst	3			3	3		
Nasal discharge discolouration	19	2	3	2	16		
Nasal discomfort	421	18	89	90	332		
Nasal disorder	52	4	16	4	36		
Nasal dryness	181	8	35	36	146		1

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Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nasal inflammation	52	6	13	22	39		
Nasal mucosa atrophy	1				1		
Nasal mucosal blistering	2		1		1		
Nasal mucosal discolouration	1				1		
Nasal mucosal disorder	23	4	5	9	18		
Nasal mucosal erosion	2		1		1		
Nasal mucosal hypertrophy	1			1	1		
Nasal mucosal ulcer	2		1		1		
Nasal mucosa telangiectasia	1	1	1				
Nasal necrosis	1	1	1				
Nasal obstruction	129	10	34	19	95		
Nasal odour	9	2	5	1	4		
Nasal oedema	148	6	46	19	102		
Nasal polyps	13	3	7	3	6		
Nasal pruritus	137	4	33	22	104		
Nasal septum deviation	8		2	2	6		
Nasal turbinate abnormality	1				1		
Nasal turbinate hypertrophy	7	1	1		6		
Nasal ulcer	11		1	4	10		
Nasopharyngeal reflux	1			1	1		
Neonatal anoxia	2		2				
Neonatal asphyxia	6	2	6			1	1
Neonatal aspiration	1		1				
Neonatal dyspnoea	1				1		
Neonatal hypoxia							1
Neonatal pneumothorax	3		3				
Neonatal respiratory acidosis	1		1				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neonatal respiratory distress	6	2	6			3	5
Neonatal respiratory distress syndrome	3	3	3			4	4
Neonatal respiratory failure	1		1				
Neonatal tachypnoea	1		1			1	2
Nocturnal dyspnoea	52	5	22	9	30		
Non-cardiogenic pulmonary oedema	1		1				
Obliterative bronchiolitis	1		1				
Obstructive airways disorder	206	30	136	29	70		1
Obstructive sleep apnoea syndrome	17	2	7	3	10		
Organising pneumonia	87	33	87				
Oropharyngeal blistering	56	10	56				
Oropharyngeal cobble stone mucosa	1		1				
Oropharyngeal discomfort	2938	75	940	355	1998	1	1
Oropharyngeal oedema	29	1	17	1	12		
Oropharyngeal pain	18845	699	3409	3731	15436	27	67
Oropharyngeal plaque	18	2	9	3	9		
Oropharyngeal spasm	22	2	16	1	6		
Oropharyngeal swelling	49	2	15	8	34		
Orthopnoea	162	30	95	29	67		
Painful respiration	717	71	256	178	461	2	2
Paranasal cyst	7	4	4	1	3		
Paranasal sinus discomfort	342	13	62	74	280		
Paranasal sinus haemorrhage	6	1	2	1	4		
Paranasal sinus hypersecretion	36	1	5	6	31		
Paranasal sinus hyposecretion	2			1	2		
Paranasal sinus inflammation	39	3	9	12	30		1
Paranasal sinus mucosal hypertrophy	1			1	1		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pharyngeal cyst	3		3				
Pharyngeal disorder	82	3	23	9	59		
Pharyngeal dyskinesia	1	1	1				
Pharyngeal enanthema	19	1	7	3	12		
Pharyngeal erosion	1				1		
Pharyngeal erythema	206	14	63	32	143		
Pharyngeal haematoma	1	1	1				
Pharyngeal haemorrhage	21	10	21				
Pharyngeal hypoaesthesia	253	10	89	37	164		
Pharyngeal inflammation	143	11	39	37	104		
Pharyngeal lesion	3		1		2		
Pharyngeal leukoplakia	1				1		
Pharyngeal mass	46	2	19	4	27		
Pharyngeal oedema	392	29	208	45	184	1	3
Pharyngeal paraesthesia	518	15	174	71	344	1	5
Pharyngeal stenosis	22	1	22				
Pharyngeal swelling	2709	166	1085	363	1624	1	3
Pharyngeal ulceration	46	4	19	3	27		
Phonasthenia	1			1	1		
Pickwickian syndrome	2	1	2				
Platypnoea	3		1		2		
Pleural adhesion	1	1	1				
Pleural disorder	9		4	2	5		
Pleural effusion	982	213	744	83	238	3	10
Pleural fibrosis	3		3				
Pleural mass	1	1	1				
Pleural rub	4		2		2		1

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pleural thickening	18	4	12	3	6		
Pleurisy	416	64	268	64	148		5
Pleuritic pain	375	29	138	104	237		1
Pneumomediastinum	15	4	15				
Pneumonitis	328	74	222	47	106	6	7
Pneumonitis aspiration	5		5				
Pneumothorax	154	44	154			1	2
Pneumothorax spontaneous	30	11	30				
Productive cough	1702	129	499	373	1203	2	8
Prolonged expiration	10		7	1	3		
Pulmonary air leakage	1				1		
Pulmonary alveolar haemorrhage	46	13	46				
Pulmonary arterial hypertension	30	11	30			1	1
Pulmonary artery dilatation	7	4	7				
Pulmonary artery occlusion	5		5				
Pulmonary artery thrombosis	38	10	38				1
Pulmonary calcification	4			2	4		
Pulmonary cavitation	3		3				
Pulmonary congestion	198	50	198			1	1
Pulmonary embolism	7227	2042	7225	1	2	24	51
Pulmonary eosinophilia	1		1				
Pulmonary fibrosis	81	21	81			3	3
Pulmonary granuloma	10	3	8	1	2		
Pulmonary haematoma	1	1	1				
Pulmonary haemorrhage	44	13	44				
Pulmonary hilum mass	2		1	1	1		
Pulmonary hypertension	131	40	131				5

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pulmonary hypertensive crisis	2		2				
Pulmonary hypoperfusion	5	3	5				
Pulmonary infarction	304	70	304				
Pulmonary mass	112	19	52	21	60	3	3
Pulmonary microemboli	12	3	12				
Pulmonary necrosis	2		2				
Pulmonary oedema	542	149	542			1	2
Pulmonary pain	1059	86	299	275	760	1	3
Pulmonary pneumatocele	1	1	1				
Pulmonary sarcoidosis	25	14	24		1		
Pulmonary sensitisation	4		2		2		
Pulmonary thrombosis	327	74	327			2	6
Pulmonary toxicity	7	2	7				
Pulmonary vascular disorder	3		1	2	2		
Pulmonary vasculitis	6	2	6				
Pulmonary veno-occlusive disease	1	1	1				
Pulmonary venous thrombosis	6	1	6				
Rales	170	18	97	24	73	2	3
Reflux laryngitis	9	2	5	2	4		
Respiration abnormal	656	139	290	176	366		
Respiratory acidosis	46	3	34	4	12		
Respiratory alkalosis	47	3	29	6	18		
Respiratory arrest	372	62	372				1
Respiratory depression	41	12	41				
Respiratory depth decreased	11	1	3	3	8		
Respiratory depth increased	1			1	1		
Respiratory disorder	1158	103	587	220	571	1	1

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Respiratory disorder neonatal	1		1			1	2
Respiratory distress	2222	323	2222			7	14
Respiratory failure	864	208	863	1	1	3	7
Respiratory fatigue	82	6	41	10	41		
Respiratory fremitus	1		1				
Respiratory gas exchange disorder	5	2	3	1	2		
Respiratory muscle weakness	17	5	14	1	3		
Respiratory paralysis	5	3	5				
Respiratory symptom	248	8	90	32	158		
Respiratory tract congestion	159	6	33	20	126	2	3
Respiratory tract haemorrhage	12	6	12				
Respiratory tract inflammation	20	1	4	6	16		
Respiratory tract irritation	99	7	24	19	75	1	1
Respiratory tract oedema	83	15	83				
Restrictive pulmonary disease	6	2	5	1	1		
Reversible airways obstruction	4	1	4				
Rheumatoid arthritis-associated interstitial lung disease	2	1	2				
Rheumatoid lung	1		1				
Rhinalgia	186	9	37	39	149		
Rhinitis allergic	218	15	40	53	178		
Rhinitis atrophic	1				1		
Rhinitis perennial	4			3	4		
Rhinorrhoea	9542	228	1250	1703	8292	8	26
Rhonchi	67	7	26	21	41	1	1
Sinonasal obstruction	36	4	14	9	22		
Sinus congestion	338	15	85	74	253	4	4
Sinus disorder	285	14	62	39	223	1	1

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Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sinus pain	619	44	226	109	393		1
Sinus polyp	6	1	1	3	5		
Sleep apnoea syndrome	147	17	54	43	93	2	2
Small airways disease	4			4	4		
Sneezing	2285	81	414	431	1871	2	9
Snoring	80	7	26	21	54		
Sputum decreased	1				1		
Sputum discoloured	89	6	33	10	56	1	2
Sputum increased	72	7	26	12	46		
Sputum retention	40	2	18	8	22		
Status asthmaticus	11	4	11				
Stertor	18		11	1	7		
Stridor	282	12	189	17	93		
Suffocation feeling	306	32	133	57	173		
Systemic sclerosis pulmonary	1	1	1				
Tachypnoea	906	66	504	94	402		
Thoracic haemorrhage	3		3				
Throat clearing	82	2	22	15	60		
Throat irritation	3560	121	883	602	2677	2	6
Throat lesion	15		2	1	13		
Throat tightness	3462	225	1623	363	1839	6	24
Tonsillar cyst	2	1	1		1		
Tonsillar disorder	51	1	10	6	41		
Tonsillar erythema	32	2	11	6	21		
Tonsillar exudate	2			1	2		
Tonsillar haemorrhage	5	1	5				
Tonsillar hypertrophy	394	24	105	69	289		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tonsillar inflammation	97	5	13	44	84		
Tonsillar ulcer	6		3		3		
Tonsillolith	12		3	4	9		
Tracheal calcification	1			1	1		
Tracheal compression	3		3				
Tracheal dilatation	1			1	1		
Tracheal disorder	10	2	3	3	7		
Tracheal inflammation	16	1	4	5	12		
Tracheal oedema	9	6	9				
Tracheal pain	28	2	7	9	21		
Tracheal stenosis	16	2	16				
Tracheomalacia	1		1				
Transient tachypnoea of the newborn	1	1	1			1	1
Upper-airway cough syndrome	132	9	32	19	100	1	3
Upper airway obstruction	35	1	35				1
Upper respiratory tract congestion	145	4	27	11	118		
Upper respiratory tract inflammation	41	1	9	8	32		
Upper respiratory tract irritation	8		2	1	6		
Use of accessory respiratory muscles	71	3	44	4	27		
Vasomotor rhinitis	5			1	5		
Velopharyngeal incompetence	1		1				
Vocal cord atrophy	1		1				
Vocal cord cyst	1	1	1				
Vocal cord disorder	44	3	13	14	31		
Vocal cord dysfunction	16		7	7	9		
Vocal cord inflammation	13	3	5	3	8		
Vocal cord thickening	4		1	1	3		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Wheezing	2252	255	1227	218	1025	4	6
Yawning	191	8	55	30	136		
Total:	190720	18154	72728	37992	117992	301	768

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acantholysis	1		1				
Acanthosis	2	1	1	1	1		
Acanthosis nigricans	1				1		
Achromotrichia acquired	3		2		1		
Acne	1219	60	200	419	1019	2	3
Acne conglobata	4	3	4				
Acne cystic	65	6	20	18	45		
Acquired epidermolysis bullosa	4	1	4				
Acquired perforating dermatosis	1		1				
Actinic cheilitis	2				2		
Actinic keratosis	8		1	5	7	1	1
Acute cutaneous lupus erythematosus	6	1	6				
Acute febrile neutrophilic dermatosis	37	9	37				
Acute generalised exanthematous pustulosis	44	10	44				
Adiposis dolorosa	2		1		1		
Alopecia	4330	358	705	2284	3625	3	6
Alopecia areata	501	69	131	212	370		
Alopecia scarring	1			1	1		
Alopecia totalis	26	5	11	9	15		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Alopecia universalis	26	5	9	10	17		
Androgenetic alopecia	18	1	7	8	11		
Angiodermatitis	2	2	2				
Angioedema	2554	676	2553		1	4	13
Angiokeratoma	1			1	1		
Angiolymphoid hyperplasia with eosinophilia	2			1	2		
Anhidrosis	16	4	8	3	8		
Aquagenic pruritus	1			1	1		
Aquagenic wrinkling of palms	2			1	2		
Argyria	1				1		
Aseptic pustule	1			1	1		
Asteatosis	1			1	1		
Autoimmune blistering disease	4	2	4				
Autoimmune dermatitis	5	1	1	3	4		
Blister	2499	160	719	471	1780	2	4
Blister rupture	15			2	15		
Blood blister	142	12	47	18	95		
Brachioradial pruritus	2			1	2		
Bromhidrosis	2			1	2		
Brow ptosis	4		1		3		
Bullous haemorrhagic dermatosis	15	7	15				
Butterfly rash	43	5	15	2	28		1
Cafe au lait spots	1				1		
Capillaritis	18	1	3	5	15		
Cellulite	7		1	1	6		
Chloasma	9			4	9		
Chronic cutaneous lupus erythematosus	25	14	25			2	2

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chronic pigmented purpura	20	2	3	4	17		
Chronic spontaneous urticaria	60	12	26	21	34		
Circumoral oedema	33	1	11	4	22		1
Circumoral swelling	69	2	21	14	48		
Cold sweat	4193	241	1451	771	2742	2	7
Cold urticaria	68	6	23	22	45		
Confluent and reticulate papillomatosis	2			2	2		
Cullen's sign	1		1				
Cutaneous contour deformity	3			3	3		
Cutaneous lupus erythematosus	10	4	10				
Cutaneous sarcoidosis	18	7	18				
Cutaneous symptom	67	1	17	10	50		
Cutaneous vasculitis	247	86	245		2		
Cutis laxa	1				1		
Dandruff	38	1	3	12	35		
Decubitus ulcer	55	9	33	5	22		
Dermal cyst	58	5	14	19	44		1
Dermatitis	904	82	264	221	640	1	1
Dermatitis acneiform	140	6	21	48	119		
Dermatitis allergic	1223	102	403	239	820	2	4
Dermatitis atopic	318	45	107	86	211		1
Dermatitis bullous	306	92	306				6
Dermatitis contact	185	17	45	35	140		
Dermatitis diaper	11	1	5	3	6		
Dermatitis exfoliative	19	3	19				
Dermatitis exfoliative generalised	65	20	65				
Dermatitis herpetiformis	19	4	8	3	11		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dermatitis psoriasiform	70	14	24	23	46		
Dermatomyositis	96	48	96				
Dermatosis	42	4	10	8	32	1	2
Diabetic foot	6	4	5	1	1		
Diabetic ulcer	1			1	1		
Diabetic wound	1		1				
Diffuse alopecia	110	17	27	52	83		
Diffuse cutaneous mastocytosis	2	1	1		1		
Digital pulpitis	2		2				
Drug eruption	411	24	152	46	259		
Drug reaction with eosinophilia and systemic symptoms	39	15	39				1
Dry skin	1140	98	273	296	867	2	10
Dyshidrotic eczema	115	6	34	29	81		
Ecchymosis	554	37	164	117	390		3
Eczema	2743	213	610	715	2133	1	4
Eczema asteatotic	30	3	7	10	23		
Eczema infantile	6		2	1	4		
Eczema nummular	64	12	20	20	44		
Eczema vesicular	10		4	5	6		
Eczema weeping	22	3	7	10	15		
Eosinophilic cellulitis	14	5	8	5	6		
Eosinophilic pustular folliculitis	3				3		
Ephelides	6			2	6	1	1
Epidermal necrosis	8	3	8				
Epidermolysis	3		3				
Erythema	21900	741	4483	3395	17417	17	58
Erythema ab igne	1				1		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Erythema annulare	24		3	8	21		
Erythema elevatum diutinum	2				2		
Erythema marginatum	2				2		
Erythema multiforme	496	178	496			3	3
Erythema nodosum	339	41	132	88	207		
Erythematotelangiectatic rosacea	2	1	1		1		
Erythrodermic psoriasis	16	4	9	4	7		1
Erythrosis	13		1	5	12		
Excessive granulation tissue	3	1	3				
Exfoliative rash	89	8	38	18	51		
Fingerprint loss	3		1	1	2		
Fixed eruption	26	5	7	7	19		
Flagellate dermatitis	1			1	1		
Follicular eczema	1		1				
Follicular mucinosis	2	1	1		1		
Fracture blisters	1				1		
Fungating wound	1	1	1				
Generalised bullous fixed drug eruption	3	1	3				
Granuloma annulare	66	8	18	23	48		
Granuloma skin	8	1	1	2	7		
Guttate psoriasis	82	19	35	22	47		
Haematidrosis	1			1	1		
Haemorrhage subcutaneous	260	33	260				
Haemorrhage subepidermal	2	1	1		1		
Haemorrhagic urticaria	5		5				
Haemosiderin stain	2			1	2		
Hair colour changes	46	3	5	14	41		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hair disorder	42	4	7	15	35		
Hair growth abnormal	63	6	11	25	52		
Hair growth rate abnormal	2	1	1	1	1		
Hair texture abnormal	59	2	8	24	51		
Hand dermatitis	91	9	21	28	70		
Hangnail	1				1		
Heliotrope rash	1		1				
Henoch-Schonlein purpura	160	44	105	22	55		
Herpes gestationis	3	1	2		1		
Hidradenitis	61	9	23	15	38	5	6
Hirsutism	13		3	5	10		
Hyperhidrosis	16936	997	4455	3574	12481	17	53
Hyperkeratosis	36	9	12	9	24	2	2
Hypersensitivity vasculitis	54	12	54				
Hypertrichosis	21	2	3	7	18		
Hypertrophic scar	3	1	1	1	2		1
Hypohidrosis	15	2	6	4	9		
Hypotrichosis	15		2	6	13		
Ichthyosis acquired	6	4	5	1	1		
Idiopathic angioedema	6	1	6				
Idiopathic urticaria	11	3	8	1	3		
Immune-mediated dermatitis	1		1				
Ingrowing nail	5	1	1	1	4	1	1
Ingrown hair	3		1		2		
Interstitial granulomatous dermatitis	2	1	1		1		
Intertrigo	10		1	2	9		
Ischaemic skin ulcer	2	1	2				

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Itching scar	24	2	4	7	20		
Jessner's lymphocytic infiltration	3	3	3				
Keloid scar	10		2	1	8		
Keratoderma blenorrhagica	1	1	1				
Keratolysis exfoliativa acquired	3	1	1		2		
Keratosis pilaris	17	2	5	2	12		
Koebner phenomenon	5		1		4		
Koilonychia	1				1		
Lentigo	1				1		
Leukoderma	2		1		1		
Leukoplakia	6	1	2	3	4		
Lichenification	4	1	1	1	3		
Lichenoid keratosis	53	14	22	16	31		
Lichen planopilaris	15	7	8	4	7		
Lichen planus	234	35	67	108	167		
Lichen sclerosus	95	14	33	39	62		
Lichen striatus	4			1	4		
Linear IgA disease	2		2				
Lipoatrophy	5		3		2		
Lipodystrophy acquired	1		1				
Lipohypertrophy	2		2				
Livedo reticularis	218	22	86	32	132		1
Lividity	55	11	27	10	28		
Lupus miliaris disseminatus faciei	1	1	1				
Lymphomatoid papulosis	6	1	2	2	4		
Macule	136	6	22	42	114		
Madarosis	64	9	23	20	41		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mechanical urticaria	159	15	40	54	119		2
Mechanic's hand	1		1				
Melanoderma	3		1	2	2		
Milia	4		2		2		
Miliaria	249	20	74	27	175		
Morbihan disease	1				1		
Mucocutaneous disorder	2				2		
Mucocutaneous haemorrhage	3	1	3				
Mucocutaneous rash	2		1	1	1		
Mucocutaneous ulceration	1		1				
Mucous membrane pemphigoid	2	2	2				
Myxoid cyst	1				1		
Nail bed bleeding	10	1	2	2	8		
Nail bed disorder	4		2		2		
Nail bed inflammation	8	1	1	5	7		
Nail bed tenderness	2		1		1		
Nail cuticle fissure	1				1		
Nail discolouration	100	6	21	23	79		
Nail discomfort	6			3	6		
Nail disorder	49	4	11	25	38		
Nail dystrophy	3			2	3		
Nail fold inflammation	1				1		
Nail growth abnormal	10	2	3	3	7		
Nail hypertrophy	1			1	1		
Nail necrosis	1		1				
Nail pigmentation	6	2	4	1	2		
Nail pitting	1			1	1		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nail psoriasis	13	2	3	7	10		
Nail ridging	12	1	4	6	8		
Necrobiosis lipoidica diabeticorum	1		1				
Necrolytic migratory erythema	1	1	1				
Necrotic angiodermatitis	1		1				
Needle track marks	12		2	3	10		
Neurodermatitis	343	23	31	242	312	1	1
Neuropathic pruritus	3	2	3				
Neutrophilic dermatosis	11	2	6	2	5		
Night sweats	3443	345	963	880	2480	3	11
Nikolsky's sign	3		3				
Nodular rash	15	1	3	5	12		
Oculomucocutaneous syndrome	42	1	42				
Oedema blister	5		1	3	4		
Oil acne	2	2	2				
Onychalgia	23	3	8	4	15		
Onychoclasis	40	1	6	23	34	1	1
Onycholysis	25	3	11	7	14		
Onychomadesis	24	4	7	9	17		
Pain of skin	1940	160	538	432	1402	1	4
Palmar erythema	107	4	27	13	80		
Palmar-plantar erythrodysaesthesia syndrome	39	4	9	12	30		
Palmoplantar keratoderma	2	1	1	1	1		
Palmoplantar pustulosis	22	3	11	7	11		
Palpable purpura	12	2	9	1	3		
Panniculitis	51	30	51				
Papule	657	25	115	120	542		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Papulopustular rosacea	9	2	3	6	6		
Paradoxical psoriasis	1		1				
Parakeratosis	7	1	1	5	6		
Paraneoplastic dermatomyositis	1		1				
Parapsoriasis	35	9	13	12	22		
Partial lipodystrophy	1			1	1		
Pathergy reaction	4		2		2		
Peau d'orange	3			1	3		
Pemphigoid	222	72	222			1	2
Pemphigus	78	35	78				
Penile ulceration	5	1	1	1	4		
Perioral dermatitis	35	2	9	14	26		
Pernio-like erythema	31	7	8	9	23		
Petechiae	1949	136	613	420	1336	4	7
Photodermatosis	4				4		
Photosensitivity reaction	600	35	172	148	428		3
Pigmentation disorder	180	10	31	41	149		
Piloerection	195	12	49	50	146		
Pityriasis	47	4	16	9	31		
Pityriasis alba	3			1	3		
Pityriasis lichenoides et varioliformis acuta	15	6	8	5	7		
Pityriasis rosea	652	36	108	230	544		
Pityriasis rubra pilaris	16	6	7	7	9		
Plantar erythema	16	1	5	2	11		
Poikiloderma	1				1		
Polymorphic eruption of pregnancy	1	1	1				
Polymorphic light eruption	17	2	5	4	12		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Post inflammatory pigmentation change	6	1	2	1	4		
Progressive facial hemiatrophy	1	1	1				
Progressive macular hypomelanosis	2		1		1		
Prurigo	93	6	18	19	75		
Pruritus	36607	1491	7307	7278	29300	30	82
Pruritus allergic	58	6	16	20	42		
Pseudofolliculitis	6		2		4		
Pseudoporphyria	1	1	1				
Psoriasis	1368	197	446	423	922	12	21
Purpura	760	68	285	108	475		2
Purpura fulminans	1	1	1				
Purpura senile	4	2	3	1	1		
Pustular psoriasis	40	16	27	5	13		
Pyoderma gangrenosum	19	8	19				
Rash	41841	1766	7661	11828	34180	36	78
Rash erythematous	4810	298	1287	753	3523	3	8
Rash follicular	4	2	3	1	1		
Rash macular	3125	159	697	645	2428	4	7
Rash maculo-papular	956	53	256	270	700	1	3
Rash maculovesicular	10		2	4	8		
Rash morbilliform	236	5	55	43	181	1	1
Rash neonatal	4		2	1	2		
Rash papular	1675	67	339	291	1336	1	4
Rash papulosquamous	10	1	2	3	8		
Rash pruritic	7514	354	1393	1839	6121	10	21
Rash rubelliform	14	4	9	4	5		
Rash scarlatiniform	11	3	3	4	8		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Rash vesicular	846	52	196	207	650	1	3
Reactive perforating collagenosis	1				1		
Rebound atopic dermatitis	1				1		
Rebound eczema	1				1		
Rebound psoriasis	3			1	3		
Reticular erythematous mucinosis	1				1		
Rosacea	192	21	48	57	144		
Sarcoid-like reaction	4	1	2	2	2		
Scab	225	13	44	33	181	2	2
Scar discomfort	16	1	2	14	14		
Scar pain	81	5	17	24	64		
Scleroderma associated digital ulcer	1		1				
Scleroedema	1	1	1				
Sebaceous gland disorder	2			1	2		
Sebaceous glands overactivity	1			1	1		
Seborrhoea	46	3	11	13	35		
Seborrhoeic dermatitis	55	3	13	23	42		
Segmented hyalinising vasculitis	9	3	9				
Sensitive skin	9591	85	544	349	9047	1	3
Septal panniculitis	1		1				
Shagreen skin	1				1		
Skin atrophy	34		5	9	29	1	1
Skin burning sensation	1890	136	458	440	1432	1	4
Skin degenerative disorder	1			1	1		
Skin depigmentation	81	6	17	22	64		
Skin discharge	10		3		7		
Skin discolouration	1718	118	433	345	1285	2	4

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skin discomfort	189	6	21	78	168		
Skin disorder	1931	219	578	760	1353	3	5
Skin erosion	84	9	36	16	48		
Skin exfoliation	967	67	261	247	706		1
Skin fibrosis	1				1		
Skin fissures	126	10	33	26	93	1	2
Skin fragility	4			1	4	1	2
Skin haemorrhage	318	23	78	76	240		
Skin hyperpigmentation	67	4	8	23	59		
Skin hyperplasia	1			1	1		
Skin hypertrophy	66	10	20	24	46		
Skin hypopigmentation	13	1	2	1	11		
Skin indentation	20	1	4	5	16		
Skin induration	73	2	10	14	63		
Skin irritation	619	42	147	134	472	1	2
Skin laxity	10	2	3	1	7		
Skin lesion	658	56	188	130	470	1	6
Skin lesion inflammation	7	1	4	1	3		
Skin maceration	1			1	1		
Skin mass	329	28	81	78	248	4	4
Skin necrosis	41	16	41				
Skin odour abnormal	184	8	26	68	158		
Skin oedema	59	5	14	11	45		
Skin plaque	120	7	33	29	87	2	2
Skin reaction	1066	41	201	235	865		1
Skin sensitisation	172	6	34	29	138		
Skin striae	21	2	8	2	13		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skin swelling	428	28	105	85	323	1	2
Skin texture abnormal	25	1	2	9	23		
Skin tightness	208	9	51	40	157		1
Skin ulcer	185	34	108	31	77		2
Skin ulcer haemorrhage	2	1	1	1	1		
Skin warm	922	69	264	135	658		2
Skin weeping	75	16	38	16	37	1	1
Skin wrinkling	55	7	18	12	37		
Solar dermatitis	26		6	7	20		
Solar lentigo	13		5	4	8		
Solar urticaria	13	1	2	6	11		
Spider naevus	4		1	1	3		
Splinter haemorrhages	7	1	3		4		
Stasis dermatitis	9	2	4	1	5		
Stevens-Johnson syndrome	78	22	78				
Sticky skin	16		3	5	13		
Subacute cutaneous lupus erythematosus	10	5	10				
Subcorneal pustular dermatosis	3		2	1	1		
Subcutaneous emphysema	8	1	5	1	3		
Superficial inflammatory dermatosis	18	2	8	5	10		
Sweat discolouration	5		1	2	4		
Sweat gland disorder	2		1		1		
Symmetrical drug-related intertriginous and flexural exanther	12	5	8	1	4		
Systemic lupus erythematosus rash	17	3	14		3		
Target skin lesion	10	1	10				
Telangiectasia	61	5	20	13	41		
Toxic epidermal necrolysis	26	9	26				

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Toxic skin eruption	138	28	138				
Transient acantholytic dermatosis	13	2	5	4	8		
Trichodynia	19		1	5	18		
Trichorrhexis	39	1	3	21	36		
Umbilical erythema	2		1		1		
Umbilical haematoma	1		1				
Umbilical haemorrhage	1		1				
Urticaria	21235	1035	4931	4481	16304	18	52
Urticaria aquagenic	4			3	4		
Urticaria cholinergic	17	5	5	3	12		
Urticaria chronic	261	62	125	74	136		
Urticaria contact	5		1	1	4		
Urticarial dermatitis	9		2	4	7		
Urticarial vasculitis	53	23	53				
Urticaria papular	38	3	10	8	28		
Urticaria physical	7			2	7		
Urticaria pigmentosa	2			1	2		
Urticaria pressure	10		4	3	6		
Urticaria thermal	20	4	7	5	13		
Urticaria vesiculosa	5		2	1	3		
Urticaria vibratory	1			1	1		
Vancomycin infusion reaction	2		1		1		
Vascular purpura	71	9	48	4	23	1	1
Vascular skin disorder	4		1	2	3		
Vasculitic rash	70	7	31	10	39		
Vasculitic ulcer	2	1	2				
Vitiligo	187	15	38	71	149		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Xanthelasma	2				2		
Xeroderma	3		1		2		
Yellow nail syndrome	1			1	1		
Yellow skin	138	12	40	34	98		
Total:	224633	12962	52865	49048	171768	220	559

System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aborted pregnancy	5	1	4		1		
Adolescence	1			1	1		
Alcohol use	6	1	2	3	4		
Anal sex	1		1				
Anxious parent	1			1	1		
Bedridden	1195	116	327	386	868		1
Bed sharing	1		1				
Blood product transfusion dependent	2	1	2				
Body modification	6			2	6		
Breast feeding	30		2	22	28		
Breast prosthesis user	4				4		
Caffeine consumption	2				2		
Cardiac assistance device user	1			1	1		
Caregiver	2		1	1	1		
Contraindication to medical treatment	2				2		
Contraindication to vaccination	9			3	9		
Corrective lens user	1			1	1	2	2

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System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dependence on oxygen therapy	17	4	17				
Device dependence	2	2	2				
Disability	65	14	39	12	26		1
Disease risk factor	3	1	1	1	2		
Drug abuser	1		1				
Economic problem	3		2	1	1		
Edentulous	1			1	1		
Educational problem	13	2	3	8	10		
Excessive exercise	3		1	2	2		
Exercise adequate	1			1	1		
Exercise lack of	18	2	9	6	9		
Ex-tobacco user	2				2		
Family stress	4		2	2	2		
Fasting	11	1	2	6	9		
Feeding tube user	2	1	2				
Flooding	1		1				
Hair dye user	2		1		1		
Hearing aid user	3			3	3		
Hearing disability	31	5	11	8	20		
Homosexuality	3		1	1	2		
Housebound	13	1	8	4	5		
Illiteracy	6	1	4	2	2		
Immobile	147	36	147				1
Immobilisation prolonged	2	1	2				
Impaired ability to use machinery	5			3	5		
Impaired driving ability	323	39	139	53	184	1	1
Impaired quality of life	535	70	228	144	307	2	2

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System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Impaired work ability	2213	301	932	633	1281		3
Inadequate diet	2	1	2				
Infant	1		1				
Job change	1				1		
Job dissatisfaction	34	4	10	12	24		
Joint prosthesis user	2		1	1	1		
Limb prosthesis user	2				2		
Living alone	2			1	2		
Living in residential institution	1				1		
Loss of employment	11	1	2	5	9		
Loss of personal independence in daily activities	3548	444	1445	837	2103	3	8
Marital problem	1			1	1		
Menarche	45	1	5	26	40		
Menopause	154	13	57	53	97		
Mental disability	7	1	2	3	5		
Miscarriage of partner	1			1	1		
Multigravida	1				1		
Multiparous	2			2	2		
Non-consummation	3			1	3		
Non-tobacco user	4			3	4		
Occupational problem environmental	1				1		
Orthosis user	1				1		
Overwork	6			1	6		
Paralytic disability	1		1				
Partner stress	3				3		
Patient dissatisfaction with treatment	1			1	1	1	1
Patient uncooperative	2		1		1		

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System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Physical assault	2			2	2		
Physical disability	73	9	36	13	37		
Poor personal hygiene	2	1	1	1	1		
Postmenopause	9	2	5	3	4		
Puberty	1				1		
Refusal of treatment by patient	5	2	2		3		
Refusal of vaccination	2			2	2		
Retirement	4		1	1	3		
Sick leave	257	62	72	169	185		
Sick relative	4		3	1	1		
Sight disability	39	3	14	7	25		
Sitting disability	117	13	45	28	72		
Social problem	9	1	2	4	7		
Stress at work	14		2	6	12		
Substance use	4			2	4		
Tanning	2			1	2		
Threat of redundancy	2			2	2		
Tobacco user	4				4		
Truancy	1				1		
Underimmunisation	1				1		
Unemployment	1				1		
Urinary assistance device user	1				1		
Vegan	1			1	1		
Voluntary redundancy	1				1		
Walking aid user	62	14	24	10	38		2
Walking disability	223	43	105	45	118		
Water pollution	4	1	3	1	1		

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System Organ Class

Social circumstances

Preferred Term		*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wheelchair user		29	7	16	6	13		
Wig wearer		4			3	4		
	Total:	9414	1223	3753	2568	5661	9	22

System Organ Class

SOC Not Yet Coded

Preferred Term		*Total # of Spontaneous AE*	Spontaneous	
			Nonserious	
			I	C
		1	1	1
	Total:	1	1	1

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal cavity drainage	1	1	1				
Abdominal operation	4	3	3		1		
Abdominoplasty	1	1	1				
Abortion induced	42	18	37	1	5	1	1
Abscess drainage	11	4	5	2	6		
Adrenocortical steroid therapy	5	1	1	3	4		
Airway secretion clearance therapy	1		1				
Allergy prophylaxis	1			1	1		
Allogenic stem cell transplantation	1	1	1				
Amputation	8	4	6	1	2		
Anaesthesia procedure	1			1	1		
Anal fissure excision	1	1	1				
Analgesic intervention supportive therapy	3				3		
Analgesic therapy	30			23	30		
Anaphylaxis prophylaxis	1		1				
Aneurysm repair	2	1	2				
Angioplasty	3	2	2	1	1		
Antiallergic therapy	3			2	3		
Antibiotic therapy	2			2	2		
Anticoagulant therapy	4	2	2	1	2		
Antidepressant therapy	1			1	1		
Antiemetic supportive care	1			1	1		
Antiinflammatory therapy	1			1	1		
Antiviral prophylaxis	1			1	1		
Antiviral treatment	1			1	1		
Aortic aneurysm repair	1		1				
Aortic surgery	1			1	1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aortic valve replacement	2	1	2				
Appendicectomy	13	7	12	1	1	1	1
Arm amputation	2	1	1		1		
Arterial bypass operation	1	1	1				
Arterial stent insertion	1			1	1		
Arteriovenous fistula operation	1			1	1		
Arthrodesis	4	1	1	3	3		
Artificial insemination	1				1		
Asthma prophylaxis	3		1	1	2		
Axillary lymphadenectomy	18	1	3	5	15		
Bed rest	76	5	20	26	56		
Bladder catheterisation	9	1	5	3	4		
Bladder catheter permanent	1		1				
Bone marrow transplant	2	2	2				
Botulinum toxin injection	1			1	1		
Breast conserving surgery	1	1	1				
Breast cyst drainage	1		1				
Breast operation	4	3	4				
Breast prosthesis removal	1		1				
Breast reconstruction	2	1	2				
Burn dressing	1		1				
Bursa removal	1			1	1		
Caesarean section	14	4	10	3	4	1	1
Cardiac ablation	3	2	2	1	1		
Cardiac operation	12	10	11	1	1	1	1
Cardiac pacemaker insertion	14	4	11	3	3		
Cardiac resynchronisation therapy	2	1	1	1	1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cardioversion	11	4	7	3	4		
Carotid artery stent insertion	1	1	1				
Carpal tunnel decompression	1		1				
Cataract operation	3	1	2	1	1		
Catheter placement	1			1	1		
Cautery to nose	1				1		
Central nervous system stimulation	4		2	1	2		
Cerebrospinal fluid drainage	1			1	1		
Cerebrovascular operation	1		1				
Cervical diathermy	1				1		
Cervical polypectomy	1	1	1				
Chemotherapy	4	1	1	3	3		
Chiropractic	1	1	1				
Cholecystectomy	20	11	11	6	9	1	1
Clamping of blood vessel	1				1		
Colon operation						1	1
Colostomy	2	1	1	1	1		
Compression garment application	1			1	1		
Contraception	2	1	1		1		
Contraceptive diaphragm	1				1		
Contraceptive implant	2		1		1		
Cooling therapy	1			1	1		
Corneal operation	1	1	1				
Corneal transplant	1		1				
Coronary angioplasty	1		1				
Coronary arterial stent insertion	4	4	4				
Coronary artery bypass	7	4	5	2	2	2	2

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
COVID-19 immunisation	735	112	145	461	590	3	4
COVID-19 prophylaxis	1				1		
COVID-19 treatment	1			1	1		
Cranial nerve decompression	1		1				
Craniectomy	3	1	3				
Craniotomy	1	1	1				
Cyst removal	1		1				
Dental care	2			1	2		
Dental implantation	2	1	1		1		
Dental local anaesthesia	1				1		
Dental operation	2	2	2				
Depilation	1				1		
Dermabrasion	9	3	6	1	3		
Dermal filler injection	3		1		2		
Diabetic diet	1		1				
Dialysis	4	2	3	1	1	1	1
Diverticulectomy	1	1	1				
Drainage	14		1	1	13		
Dry skin prophylaxis	1			1	1		
Ear irrigation	1		1				
Ear operation	1	1	1				
Ear tube insertion	1			1	1		
Ectopic pregnancy termination	1				1		
Electroconvulsive therapy	1	1	1				
Electrolyte substitution therapy	2			2	2		
Emergency care	3	1	2	1	1		
Empyema drainage	1				1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Endocervical curettage	1			1	1		
Endodontic procedure	3			3	3	1	1
Endometrial scratching	1				1		
Endotracheal intubation	7	1	6		1		
Endovenous ablation	1	1	1				
Epidural blood patch	1				1		
Epidural injection						1	1
Excessive dietary supplement intake	1				1		
Eyeglasses therapy	1			1	1		
Eye irrigation	2				2		
Eyelid operation	1	1	1				
Eye operation	3	2	3			3	3
Face lift	1	1	1				
Fasciectomy	1	1	1				
Finger amputation	1	1	1				
Finger repair operation	1			1	1		
Fluid intake restriction	5		3		2		
Fluid replacement	1	1	1				
Fracture reduction	1	1	1				
Frontal sinus operation	2				2		
Gallbladder operation	2	1	1	1	1		
Gastric bypass						1	1
Gastrointestinal surgery	1		1				
Gastrointestinal tube removal	1			1	1		
Gastropexy	1				1		
Gastrorrhaphy	1				1		
Gastrostomy	1	1	1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
General anaesthesia	1	1	1				
Haematoma evacuation	1	1	1				
Haemodialysis	2	1	1		1		
Hand amputation	1	1	1				
Heart valve operation	2	2	2				
Heat therapy	1			1	1		
Hernia repair	3		2	1	1		1
Hip arthroplasty	8	4	5	1	3	2	2
Hip surgery	2	1	2			2	2
Hormonal contraception	1			1	1		
Hormone replacement therapy	1		1			1	1
Hormone therapy	8		2	4	6		
Hospitalisation	17	6	16		1	2	3
Hysterectomy	7	3	5	2	2		
Ileectomy	1		1				
Ileostomy	1				1		
Immune tolerance induction	2				2		
Immunisation	46563	10949	19108	14708	27455	114	197
Immunoglobulin therapy	1	1	1				
Implantable defibrillator insertion	3	3	3				
Infusion	1				1		
Inguinal hernia repair	1		1				
Injection	20		8	2	12		
Insulin therapy	1			1	1		
Intensive care	7	5	7				
Interchange of vaccine products	38170	9189	13994	15804	24176	207	280
Internal fixation of fracture	1			1	1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Internal fixation of spine	1	1	1				
Intervertebral disc operation	1	1	1			1	1
Intestinal anastomosis	1				1		
Intestinal operation						1	1
Intestinal resection						2	3
Intra-cerebral aneurysm operation	1		1				
Intrauterine contraception	11			8	11		
Intra-uterine contraceptive device insertion	4			3	4		
Intra-uterine contraceptive device removal	1			1	1		
Intravesical immunotherapy	1	1	1				
Iridotomy	1			1	1		
Jaw lesion excision	1	1	1				
Jaw operation	1	1	1			1	1
Joint arthroplasty	1	1	1			1	1
Joint fluid drainage	2			1	2		
Joint injection	4	1	3		1		
Joint stabilisation	6		3	1	3		
Keratoplasty	1	1	1				
Knee arthroplasty	8	5	7	1	1	8	9
Knee operation	3	3	3			2	3
Labour induction	4	2	3		1		
Lactation inhibition therapy	2			2	2		
Large intestinal polypectomy	2			1	2		
Leg amputation	11	5	11				
Lens extraction	1				1		
Ligament operation	1	1	1				
Limb amputation	2		2				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Limb immobilisation	61	7	19	8	42		1
Limb operation	10	5	8	1	2		
Limb reconstructive surgery						1	1
Lip cosmetic procedure	1			1	1		
Liver transplant	1	1	1				
Local anaesthesia	11	1	4	1	7		
Localised alternating hot and cold therapy	1		1				
Lung assist device therapy	2		1	1	1		
Lung operation	1	1	1				
Lymphadenectomy	8	1	2	1	6		
Macrophage activation	2	1	2				
Magnetic therapy	1		1				
Mammoplasty	1		1				
Manual lymphatic drainage	2			2	2		
Mass excision	17		4	4	13		
Mastectomy	4	4	4				
Mechanical ventilation	3		3				
Medical diet	7		3	1	4		
Medical induction of coma	20	7	18	1	2		
Medical procedure	2		1	1	1		
Medication dilution	1				1		
Menstrual cycle management	333	6	13	180	320		
Migraine prophylaxis	2		1	1	1		
Mineral supplementation	3			3	3		
Mitral valve repair	2	1	2				
Mitral valve replacement	1	1	1				
Multiple sclerosis relapse prophylaxis	3		1	1	2		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Myomectomy	2	1	1	1	1		
Nail operation	3		2		1		
Nasal cavity packing	3				3		
Nasal septal operation	1		1				
Nasopharyngeal surgery	1		1				
Neck lift	1		1				
Nerve block	15	1	7	1	8	1	1
Neurolysis	1				1		
Nipple resection	1	1	1				
Nothing by mouth order	14			4	14		
Oesophagectomy	1				1		
Oestrogen replacement therapy	1			1	1		
Oophorectomy	2			1	2		
Oral contraception	14		2	8	12		
Oral surgery						1	1
Orchidectomy	1	1	1				
Orthodontic procedure	1			1	1		
Orthopaedic procedure	1			1	1		
Ovarian operation	1	1	1				
Ovulation induction	3	1	2	1	1		
Oxygen therapy	7		3	1	4	1	1
Palliative care	5	2	4		1		
Pancreatic operation	1	1	1				
Parathyroidectomy	1	1	1			1	1
Parenteral nutrition	2	1	1	1	1		
Patient isolation	3	1	1	1	2		
Pelvic floor stimulation	1				1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Percutaneous coronary intervention	1	1	1				
Pericardial drainage	9	4	6	3	3		
Peripheral artery surgery	1	1	1				
Peripheral nerve destruction	2			1	2		
Peripheral nerve neurostimulation	2		1	1	1		
Phlebectomy	3	2	3				
Phlebotomy	3	2	2	1	1		1
Physical fitness training	1				1		
Physiotherapy	2			1	2		
Platelet transfusion	1			1	1		
Pleural decortication	1	1	1				
Polypectomy	2	1	1	1	1		
Positive airway pressure therapy	1		1				
Positive end-expiratory pressure	1	1	1				
Posterior fossa decompression	1		1				
Postoperative analgesia	1			1	1		
Prepuce dorsal slit	1	1	1				
Probiotic therapy	1			1	1		
Product substitution	1			1	1		
Promotion of wound healing	2			1	2		
Prophylaxis of nausea and vomiting	7	1	4	1	3		
Prosthetic vessel implantation	1	1	1				
Pulmonary endarterectomy						1	1
Radical hysterectomy	1		1				
Radiotherapy	3	1	1	1	2		
Red blood cell transfusion	1				1		
Rehabilitation therapy	5	1	2	1	3		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Renal artery stent placement	1		1				
Renal surgery	3	1	2	1	1		
Renal transplant	2	2	2				
Renal tumour excision	1		1				
Resuscitation	42	23	40	1	2		
Retinal cryoablation	1			1	1		
Retinal operation	3	1	2	1	1		
Retinopexy	1	1	1				
Rotator cuff repair	1	1	1				
Routine health maintenance	1		1				
Salpingectomy	3	1	2		1		
Salpingo-oophorectomy bilateral	1	1	1				
Sclerotherapy	2	1	1	1	1		
Shoulder arthroplasty						3	4
Shoulder operation	2	2	2			2	2
Sigmoidectomy	1	1	1				
Sinus operation	3				3	2	2
Skin cosmetic procedure	1			1	1		
Skin graft	3		2		1		
Skin neoplasm excision	1			1	1		1
Skin operation	1		1				
Sleep disorder therapy	1			1	1		
Small intestinal resection	2	1	2				
Smallpox immunisation	1				1		
Specialist consultation	17			16	17		
Spinal cord operation	1	1	1				
Spinal decompression	1				1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Spinal fusion surgery	2		1		1	2	2
Spinal laminectomy	2	1	1	1	1		
Spinal operation	3	1	1	2	2	2	2
Splenic artery embolisation	2	1	2				
Stent placement	12	8	9	3	3		
Sterilisation	1	1	1				
Supine position	4	1	2	1	2		
Surgery	19	9	15	3	4	1	1
Suture insertion	1	1	1				
Tenodesis	2	1	2				
Testicular operation	1	1	1				
Therapeutic embolisation	1	1	1				
Therapeutic hypothermia	1		1				
Therapeutic procedure	2				2	2	2
Therapeutic skin care topical	1		1				
Therapy cessation	2			1	2		
Therapy change	8	1	2	5	6		
Therapy interrupted	3	1	1	2	2	2	2
Thoracic cavity drainage	1	1	1			1	1
Thrombectomy	8	2	7	1	1		
Thromboembolectomy	1	1	1				
Thrombolysis	20	6	17	3	3		
Thymectomy	1	1	1				
Thyroidectomy	3	2	2	1	1		
Thyroid hormone replacement therapy	1			1	1		
Thyroid operation	1			1	1		
Tissue sealing	1			1	1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tonsillectomy	1		1				
Tooth extraction	27	4	6	11	21		2
Tooth restoration	1	1	1				
Tracheostomy	2		1		1		
Tracheostomy tube removal	1			1	1		
Transfusion	10	6	9	1	1		
Transplant	2	2	2				
Transurethral bladder resection	1			1	1		
Transurethral prostatectomy	2	2	2				
Treatment delayed	1			1	1		
Trigeminal nerve injection	1				1		
Tumour ablation	1	1	1				
Uterine dilation and curettage	17	9	10	5	7		
Uterine dilation and evacuation	1			1	1		
Uterine operation	1			1	1		
Vagotomy	1		1				
Vascular anastomosis	1		1				
Vascular compression therapy	1			1	1		
Vascular graft	3	2	2	1	1		
Vascular operation	1	1	1				
Vasodilation procedure	1			1	1		
Vehicle solution use	1				1		
Venous operation	3	2	2	1	1		
Ventricular drainage	1	1	1				
Vestibuloplasty	1				1		
Vitamin supplementation	1			1	1		
Vitrectomy	1				1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vulvectomy	1		1				
Weight loss diet	2		1	1	1		
Wheat-free diet	1		1				
Wisdom teeth removal	2				2		
Withdrawal of life support	1	1	1				
Wound closure	1				1		
Wound drainage	1		1				
Wrist surgery	2	1	2				
Total:	87073	20622	33934	31464	53139	385	553

System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Accelerated hypertension	11	3	3	2	8		
Achenbach syndrome	16	1	3	5	13		
Acute aortic syndrome	4		4				
Air embolism	2	1	2				
Aneurysm	105	22	75	12	30		
Aneurysm arteriovenous	1		1				
Aneurysm ruptured	46	12	46				
Angiodysplasia	1		1				
Angiopathy	159	24	72	31	87		2
Aortic aneurysm	57	12	48	3	9		
Aortic aneurysm rupture	35	2	35				
Aortic arteriosclerosis	57	16	46		11	1	2
Aortic dilatation	25	3	15	5	10		

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aortic disorder	13	1	9	4	4		
Aortic dissection	138	38	138				
Aortic dissection rupture	8	3	8				
Aortic elongation	4		1		3		
Aortic embolus	6	1	6				
Aortic intramural haematoma	4	1	4				
Aortic occlusion	7	3	7				
Aortic perforation	1	1	1				1
Aortic rupture	10	3	10				
Aortic stenosis	38	6	38				
Aortic thrombosis	37	12	37				
Aortitis	25	11	25				
Arterial disorder	38	5	17	10	21		
Arterial haemorrhage	16	5	16				
Arterial insufficiency	2	2	2				
Arterial intramural haematoma	2		2				
Arterial occlusive disease	128	40	105	8	23	4	5
Arterial rupture	15	5	15				
Arterial spasm	4	1	3		1		
Arterial stenosis	28	9	28				
Arterial stiffness	1				1		
Arterial thrombosis	81	20	71	4	10		1
Arterial wall hypertrophy	1	1	1				
Arteriosclerosis	217	33	141	25	76	1	1
Arteriovenous fistula	12	4	11	1	1		
Arteritis	30	5	20	9	10		
Artery dissection	34	9	34				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Atheroembolism	3	1	3				
Atherosclerotic plaque rupture	6	2	6				
Axillary vein thrombosis	33	10	30		3		1
Behcet's syndrome	48	18	48			1	3
Bleeding varicose vein	7	1	4	2	3		
Blood pressure fluctuation	1079	133	370	322	709	5	5
Blood pressure inadequately controlled	46	2	16	9	30		1
Bloody discharge	87	7	33	18	54		
Blue toe syndrome	69	7	29	12	40		
Brachial artery entrapment syndrome	1				1		
Brachiocephalic artery occlusion	1		1				
Brachiocephalic artery stenosis	1		1				
Brachiocephalic vein occlusion	1		1				
Brachiocephalic vein thrombosis	10	5	10				
Calcium embolism	2		2				
Capillary disorder	42	4	8	11	34		
Capillary fragility	127	9	32	35	95		
Capillary leak syndrome	62	24	62			1	1
Carotidynia	8			5	8		
Circulatory collapse	1482	540	1482			6	13
Circulatory failure neonatal	1	1	1				
Claudication of jaw muscles	10		3	2	7		
Collateral circulation	3				3		
Cryoglobulinaemia	14	6	14				
CT hypotension complex	2		2				
Cyanosis	1027	120	519	180	508	1	3
Deep vein thrombosis	4696	1304	4694	1	2	16	32

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dependent rubor	8		1	4	7		
Diabetic vascular disorder	1		1				
Dialysis hypotension	1	1	1				
Diastolic hypertension	20	3	14	2	6		
Diastolic hypotension	5		4		1		
Diffuse vasculitis	11	4	8	2	3		
Distributive shock	3		3				
Dry gangrene	3	2	3				
Embolism	353	103	353				2
Embolism arterial	42	14	42				
Embolism venous	62	20	62				1
Endocrine hypertension	1	1	1				
Endothelial dysfunction	11	2	5	3	6		
Erythromelalgia	25	1	12	6	13		
Essential hypertension	33	12	26	3	7		1
Exsanguination	2		2				
Extravasation blood	17	3	5	4	12		
Extremity necrosis	21	7	17	2	4		
False lumen dilatation of aortic dissection	1		1				
Femoral artery embolism	6		6				
Fibromuscular dysplasia	6	2	4		2		
Flushing	3821	148	970	427	2851	4	14
Giant cell arteritis	268	74	219	28	49		
Granulomatosis with polyangiitis	39	22	39				
Haematocoele	1			1	1		
Haematoma	2860	171	636	771	2224	1	5
Haemodynamic instability	49	13	38	5	11		

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System Organ Class

Vascular disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemodynamic rebound	1		1				
Haemorrhage	2586	668	2585	1	1	9	22
Haemorrhage neonatal	3	1	3				
Haemorrhagic infarction	21	7	21				
Haemorrhagic vasculitis	2		2				
Hot flush	7550	272	1410	1753	6140	9	17
Hyperaemia	159	8	36	30	123		5
Hypertension	14859	1409	6255	2757	8604	32	64
Hypertensive angiopathy	2		2				
Hypertensive crisis	1560	334	1559		1	6	14
Hypertensive emergency	54	12	54				1
Hypertensive urgency	45	23	45			1	1
Hypoperfusion	23	1	14	4	9		
Hypotension	5707	427	2401	937	3306	6	24
Hypotensive crisis	23	1	23				
Hypovolaemic shock	92	3	92				
Iliac artery arteriosclerosis	1	1	1				
Iliac artery occlusion	9	4	8	1	1		
Iliac artery rupture	1	1	1				
Iliac artery stenosis	5	3	5				
Infarction	163	60	163				
Inferior vena cava dilatation	10	4	7	1	3		
Inferior vena caval occlusion	4	1	4				
Inferior vena cava stenosis	1		1				
Inferior vena cava syndrome	2		2				
Intermittent claudication	64	1	32	17	32		
Internal haemorrhage	240	46	240			1	3

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ischaemia	204	52	164	15	40	2	5
Ischaemic limb pain	6	2	4	1	2		
Jugular vein distension	26	2	12	6	14		
Jugular vein embolism	1		1				
Jugular vein haemorrhage	1		1				
Jugular vein occlusion	4		3	1	1		
Jugular vein thrombosis	85	29	80		5		2
Kawasaki's disease	27	13	27				
Labile blood pressure	88	14	42	23	46		
Labile hypertension	31	2	6	13	25		
Leriche syndrome	3	1	3				
Lower limb artery perforation	1		1				
Lupus vasculitis	3	2	2		1		
Lymphangiectasia	3		1	1	2		
Lymphangiopathy	3		3				
Lymphatic fistula	3	1	3				
Lymphocele	12	1	2	1	10		
Lymphoedema	810	76	229	191	581	4	7
Lymphorrhoea	8	3	6	1	2		
Lymphostasis	13	2	3	3	10		
Macroangiopathy	5		2	3	3		
MAGIC syndrome	2	1	2				
Malignant hypertension	19	4	19				
May-Thurner syndrome	9	3	7	1	2		
Microangiopathy	36	9	21	4	15		
Microembolism	22	5	22				1
Microscopic polyangiitis	29	9	23	5	6		

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Vascular disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Necrosis ischaemic	1		1				
Necrosis of artery	1	1	1				
Neonatal hypotension	1	1	1				
Neovascularisation	5		3	2	2		
Neurogenic shock	45	9	45				
Non-dipping	2			1	2		
Obstructive shock	5		5				
Orthostatic hypertension	11	1	9	1	2		
Orthostatic hypotension	291	20	116	44	175		1
Paget-Schroetter syndrome	5	2	5				
Pallor	3300	218	1210	645	2090	6	12
Paradoxical embolism	7	1	6	1	1		
Paradoxical pressor response	1			1	1		
Paraneoplastic thrombosis	1		1				
Pelvic venous thrombosis	106	42	106				
Peripheral arterial occlusive disease	68	19	52	10	16		
Peripheral artery aneurysm	9	2	7	1	2		1
Peripheral artery aneurysm rupture	2	1	2				
Peripheral artery dissection	2	1	2				
Peripheral artery haematoma	1	1	1				
Peripheral artery occlusion	43	19	43				1
Peripheral artery stenosis	9	4	9				
Peripheral artery thrombosis	149	34	132	11	17		
Peripheral circulatory failure	114	14	49	14	65	1	1
Peripheral coldness	2701	184	807	536	1894	1	7
Peripheral embolism	69	14	60	4	9		
Peripheral ischaemia	199	36	137	24	62		

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System Organ Class

Vascular disorders

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Peripheral vascular disorder	650	43	119	184	531	5	6
Peripheral vein occlusion	1	1	1				
Peripheral vein stenosis	2		2				
Peripheral vein thrombus extension	3	1	3				
Peripheral venous disease	232	38	96	49	136		
Periphlebitis	9		1	1	8		
Phlebitis	643	96	313	129	330	3	4
Phlebitis deep	12	1	9	1	3		1
Phlebitis superficial	114	18	50	18	64		
Phlebolith	3		1	2	2		
Plethoric face	1				1		
Polyarteritis nodosa	14	7	14				
Poor peripheral circulation	236	27	79	75	157	1	1
Poor venous access	6		2		4	1	5
Postpartum venous thrombosis	2	1	2				
Post thrombotic syndrome	15	2	8	6	7		
Prehypertension	5		1		4		
Pseudovasculitis	2				2		
Raynaud's phenomenon	444	67	152	111	292	3	3
Reperfusion injury	1	1	1				
Rheumatoid vasculitis	1		1				
Secondary hypertension	11	2	4	1	7		
Shock	469	96	469				1
Shock haemorrhagic	37	6	37				
Shock symptom	37	12	37				
Spider vein	64	6	15	29	49		1
Subclavian artery aneurysm	1		1				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Subclavian artery dissection	1		1				
Subclavian artery embolism	1		1				
Subclavian artery occlusion	4	2	4				
Subclavian artery stenosis	2	1	2				
Subclavian artery thrombosis	11	5	11				
Subclavian vein occlusion	3	1	3				
Subclavian vein stenosis	1		1				
Subclavian vein thrombosis	100	25	100				
Superficial vein prominence	32	3	10	7	22		
Superficial vein thrombosis	976	134	598	123	378	1	5
Superior vena cava occlusion	1		1				
Superior vena cava syndrome	10	4	8	1	2		
Susac's syndrome	5		5				
Systolic hypertension	33		17	5	16		
Takayasu's arteritis	8	3	8				
Thromboangiitis obliterans	7	2	5		2		
Thrombophlebitis	840	179	535	105	305	1	1
Thrombophlebitis migrans	3	1	3				
Thrombosed varicose vein	14	2	7	1	7		
Thrombosis	4676	1442	4676			17	37
Varicophlebitis	45	3	18	8	27		
Varicose ulceration	6	2	5	1	1		
Varicose vein	493	43	133	133	360		1
Varicose vein ruptured	9	3	6	2	3		
Vascular calcification	8		5	1	3		
Vascular compression	4	1	2		2		
Vascular dissection	2	1	2				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vascular fragility	4	1	1	3	3		
Vascular insufficiency	7		3	1	4		
Vascular occlusion	45	12	28	11	17	2	2
Vascular pain	450	42	111	138	339		
Vascular rupture	50	6	21	9	29	1	1
Vascular shunt	1				1		
Vascular stenosis	8		5	1	3		
Vascular wall hypertrophy	2		2				
Vasculitis	734	155	421	110	313	1	1
Vasculitis necrotising	20	6	16	1	4		1
Vasoconstriction	43	5	20	6	23		
Vasodilatation	343	29	103	60	240		
Vasospasm	39	8	18	7	21		
Vein collapse	13	2	5	2	8	1	1
Vein discolouration	50	6	10	9	40		
Vein disorder	259	16	63	56	196		
Vein rupture	43	16	43			1	1
Vein wall hypertrophy	2		1		1		
Vena cava embolism	2		2				
Vena cava thrombosis	42	13	42				
Venoocclusive disease	1		1				
Venous aneurysm	4	2	4				
Venous haemorrhage	11	4	11				1
Venous hypertension	2		1	1	1		
Venous occlusion	52	14	38	4	14		
Venous perforation	2		2				
Venous recanalisation	1		1				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Venous stenosis	1	1	1				
Venous thrombosis	493	111	369	59	124	3	4
Venous thrombosis in pregnancy	2	1	2				
Venous thrombosis limb	741	228	610	47	131	1	6
Vessel perforation	2			2	2		
Visceral congestion	3	1	3				
White coat hypertension	7	1	3		4		
Withdrawal hypertension	7		2		5		
Total:	73542	10216	38959	10559	34583	161	367

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